CardioServ

Version 4.2

Operator's Manual

227 446 32 Revision I

GE Medical Systems
Information Technologies

The product **CardioServ** bears the CE marking

CE-0459 (notified body GMED)

indicating its conformity with the provisions of the Council Directive 93/42/EEC concerning medical devices and fulfills the essential requirements of Annex I of this directive.

The product complies with the electromagnetic immunity requirements of standard IEC 60601-1-2/EN 60601-1-2 “Electromagnetic Compatibility – Medical Electrical Equipment”.

The device is in radio-interference protection class B in accordance with CISPR11/EN 55011.

The CE marking covers only the accessories listed in section “Order Information and Accessories”.

This manual describes **CardioServ** with all options included and reflects software version 4.13.

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The country of manufacture appears on the device label.

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Revision History

This document is subject to the **GE Medical Systems** *Information Technologies* GmbH change order system. The revision code, a letter that follows the document part number, changes with every update of the manual.

Part No./Revision Code	Date	Comment
227 446 32	29 April 1997	Initial Release
227 446 32-A	14 May 1997	SW version 4.1
227 446 32-B	1 July 1997	ECO 202998
227 446 32-C	9 July 1998	ECO 060477
227 446 32-D	6 August 1999	ECO 062982
227 446 32-E	11 June 2001	ECO 066990
227 446 32-F	15 October 2003	ECO 074738
227 446 32-G	13 January 2004	ECO 075566
227 446 32-H	20 December 2004	ECO 079412
227 446 32-I	28 July 2005	ECO 080432

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General Information

* This manual is an integral part of the instrument and describes its normal use. It should always be kept close to the equipment. Observance of the manual is a prerequisite for proper instrument performance and correct operation and ensures patient and operator safety.

* The symbol ⚠ denotes: **Refer to Operator's Manual!** It serves as an indicator for important facts to be noted when operating the instrument.

* Information which refers only to certain versions of the instrument is accompanied by the part number(s) of the instrument(s) concerned. The part number is given on the instrument nameplate.

* Patient safety, specified measuring accuracy, and interference-free operation can be guaranteed only if original GEMS IT devices are interconnected (e.g. basic units and plug-in modules).

* Only use accessories which are listed in this manual or which have been tested in combination with the device (e.g. patient cables, electrodes, transducers, sensors, consumables, etc.). If you use accessories or consumables from other manufacturers, GEMS IT does not guarantee safe operation or functioning of the device.

* The warranty does not cover damage resulting from the use of accessories and consumables from other manufacturers.

* GEMS IT considers itself responsible for the effects on safety, reliability, and performance of the equipment, only if

  – assembly operations, extensions, readjustments, modifications, or repairs are carried out by GEMS IT or by persons authorized by GEMS IT

  – the instrument is used in accordance with the instructions for use.

* All publications are in conformity with the instrument specifications and IEC publications on safety of electromedical equipment valid at the time of printing. All rights are reserved for instruments, circuits, techniques, software programs and names appearing in the manual.

* On request GEMS IT will provide a service manual.

* The GEMS IT quality management system complies with the standards DIN EN ISO 9001 and EN 46001.

1. Introduction to CardioServ

This section describes

- **The capabilities and applications of the CardioServ defibrillator**
- **points to note when operating CardioServ**
- **general points to note when handling a defibrillator**

1.1 General Information

CardioServ is a high-voltage electrotherapy unit which should be handled only by specially trained personnel. Even though the defibrillator is equipped with various safety features, such as internal safety discharging, its operation by unqualified staff could be hazardous to the patient, the operator, and any assisting personnel.

☞ ***The user instructions given in this manual refer to a CardioServ unit equipped with pacemaker and SpO_2 measuring system.***

CardioServ is a light-weight, portable defibrillator with ECG monitor and built-in recorder.

The device is designed for external and internal defibrillation. It can be used both for semi-automatic and for manual defibrillation. Furthermore **CardioServ** is capable of monitoring the heart rate with adjustable alarm limits.

CardioServ can be expanded with a transcutaneous pacemaker and/or SpO_2 measuring system which also monitors the measured SpO_2 values.

The device is easy and convenient to operate. Three operating steps are sufficient to deliver the defibrillation shock. The display can be turned 180° to allow the user to view the information when the device is standing upright.

Defibrillation can be performed with standard defibrillation paddles, defibrillation pads and internal electrodes.

In addition to line power operation, the defibrillator operates on battery power from a slot-in rechargeable battery, and on 12-Volt power supplied from an emergency vehicle.

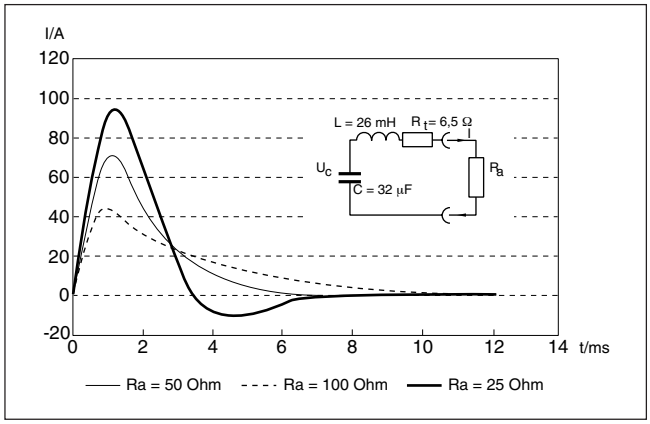

*Figure 1-1. **CardioServ** current-discharge curve (360 J)*

CardioServ comes with three memories whose contents can be documented individually:

– text memory (code summary documentation)
– event memory (16-s ECG)
– trend memory (trend plots of HR, SpO_2, 45 min, 9 hours)

The built-in recorder is initiated automatically or manually.

Extensive safety precautions have been taken to protect the patient and the user from inadvertent delivery of defibrillation shocks.

The current-discharge curve corresponds to an approximate sinusoidal halfwave with aperiodic decay. Figure 1-1 shows the discharge curve for various external resistances.

1.2 For your Safety

The safety information given below is divided into the categories “Danger”, “Warning” and “Caution”.

indicates an imminently hazardous situation which, if not avoided, will result in death or serious injury.

indicates a potentially hazardous situation which, if not avoided, could result in death or serious injury.

indicates a potentially hazardous situation which, if not avoided, may result in minor or moderate injury and/or damage to the equipment.

☞ *provides application tips or other useful information to assure that you get the most from your equipment.*

☞ *CardioServ is designed to comply with IEC 60601/ EN60601 requirements. It is Class I equipment and has an internal power source.*

CardioServ operates on line voltages between 95 and 240 Volts, 49 to 65 Hz. The mains plug must be connected to an appropriate power supply with a non-fused earthed wire. The use of extension cords is not permitted.

Before putting the device into operation, visually check all connecting cables and electrodes for signs of damage. Damaged cables and electrodes must be replaced immediately, before use.

When disconnecting the device from the power line, first remove the plug from the wall outlet.

Disconnect the device from the power line and operate it on battery power, if the integrity of the protective earth conductor is in doubt.

Set up the device in a location which affords sufficient ventilation. The ventilation openings of the device must not be obstructed. The ambient conditions specified in the “Technical Specifications” section must be ensured at all times.

Devices intended for emergency application must not be exposed to low temperatures during storage and transport to avoid moisture condensation at the application site. Wait until all moisture has vaporized before using the device. Avoid using the defibrillator under conditions where prolonged exposure to or excessive contact with moisture can occur.

Before putting the defibrillator into operation, make sure that the paddles and all connection cables are dry.

CardioServ is an emergency device and must be ready for operation at any time. For this reason, the defibrillator battery must always be charged. This can be achieved by leaving the defibrillator connected to the power line when it is not needed in an environment where only battery operation is possible.

Possible explosion hazard if used in the presence of concentrated oxygen.

CardioServ is suitable for application in a humid environment provided the regulations concerning drip-proof equipment of IEC 60601 are strictly observed. However, avoid defibrillation in a very moist or wet environment, unless absolutely necessary.

Use only the original GEMS IT batteries, as these are designed for an extended temperature range.

Magnetic and electrical fields are capable of interfering with the proper performance of the device. For this reason make sure that all external devices operated in the vicinity of the defibrillator comply with the relevant EMC requirements. X-ray equipment, MRI devices and radio systems are a possible source of interference as they may emit higher levels of electromagnetic radiation.

☞ *The defibrillator is designed for intracardiac application.*

Devices may be connected to other devices or to parts of systems only when it has been made certain that there is no danger to the patient, the operators, or the environment as a result. In those instances where there is any element of doubt concerning the safety of connected devices, the user must contact the manufacturers concerned or other informed experts as to whether there is any possible danger to the patient, the operator, or the environment as a result of the proposed combination of devices. Standards IEC 60601-1-1/ EN 60601-1-1 must be complied with in all cases.

☞ *Set up the device so that the operator has a clear, unobstructed view of the front panel.*

Liquids must not be allowed to enter the device. Devices into which liquids have penetrated must be immediately cleaned and checked by a service technician.

Danger

Use only the original GEMS IT patient cables. Do not connect other signal sources to the cables.

Caution

Patient signal inputs labelled with the ♥ symbol are protected against damage resulting from defibrillation and electrocautery voltages. Nevertheless extreme care must be taken when devices which are directly connected to the patient remain applied during electrocautery or defibrillation. The distance between ECG electrodes should be at least 15 cm. If in doubt, disconnect the patient cable from the device while applying the defibrillation pulse or performing electrocautery.

Warning

For defibrillation of children use only the special clip-on electrodes for children listed in section 15 "Order Information and Accessories".

Warning

The full responsibility for the use of accessories from other manufacturers lies with the user.

Caution

Check the device performance at regular intervals (once a month), strictly following the instructions given in section 3.2. Do not select high energy levels for test discharges with defibrillation electrodes shorted together.

Caution

For each defibrillation, verify that the selected and the displayed/charged energy are identical.

☞ *CardioServ also operates on line power when the battery is depleted or missing.*

Caution

At the end of its service life, CardioServ and its accessories must be disposed of in compliance with the special waste control regulations for electronic parts. If you have any questions in this matter, please contact GEMS IT GmbH.

Warning

Dispose of the packaging material, observing the applicable waste-control regulations and keeping it out of children's reach.

Literature

Medical Device Directive

EN 60601-1/1990 + A 1: 1993 + A2: 1995: Medical electrical equipment. General requirements for safety

EN 60601-1-1/9.1994 + A1 12/1995: General requirements for safety. Requirements for the safety of medical electrical systems.

IEC Publication 513/1994: Fundamental aspects of safety standards for medical equipment.

ROY, O.Z.: Summary of cardiac fibrillation thresholds for 60-Hz currents and voltages applied directly to the heart. Med. & Biol. Engn. & Computing 18: 657...659 (1980).

General points to note when handling a defibrillator

Electromedical equipment such as the CardioServ defibrillator must only be handled by persons who are trained in the use of such equipment and are capable of applying it properly.

Before using the equipment, the operator must ascertain that it is in correct working order and operating condition.

The defibrillator paddles must be clean and dry.

☞ *The person carrying out the defibrillation should have at least one assistant.*

The operator must be trained in the use of the defibrillator.

All assistants must be briefed regarding the preparations for and execution of defibrillation.

All tasks must be assigned clearly.

Defibrillating a patient with normal heart rhythm may induce ventricular fibrillation.

Position the patient flat on a hard, dry surface where the patient is electrically insulated. The patient must not be allowed to come into contact with metal parts, e.g., bed or litter, in order to prevent unwanted pathways for the defibrillation current which endanger the assistants. For the same reason, do not place the patient on wet ground (rain, accident in swimming pool).

☞ *Have a pacemaker at hand, if possible.*

☞ *Should cardiac arrest occur or be imminent during preparations for defibrillation, administer heart massage and artificial respiration (CPR).*

Do not allow the defibrillator paddles to come into contact with other electrodes or metal parts which are in contact with the patient.

Transducers and instruments that are not defibrillation-proof must be disconnected from the patient.

Interrupt heart massage and artificial respiration immediately before triggering the shock.

Immediately before triggering the shock disconnect tubes and have assistants step back.

The patient's chest must be dry, as moisture causes unwanted pathways for the defibrillation current. Therefore, when using flammable skin cleansing agents, wait until they have completely dried.

Possible explosion hazard if used in the presence of concentrated oxygen, flammable substances (gasoline) or anesthetic agents. Oxygenation in the vicinity of the defibrillation paddles must be strictly avoided; if necessary, interrupt oxygen supply while defibrillating the patient.

To prevent sparking

- ***the electrodes should make full contact with the body***
- ***the electrodes should be pressed firmly onto the thorax.***

Do not deliver shocks into open air. High voltage may briefly be present at the unprotected paddle surfaces as a result and endanger the persons present.

When defibrillating children it is especially important to verify that the paddles make full contact with the body surface. This is to be observed also when using the clip-on electrodes for children (Part No. 303 439 95).

Defibrillating a patient who has an implanted pacemaker is likely to impair the pacemaker function or cause damage to the pacemaker. Therefore, the following should be observed:

- *Select the smallest energy level possible for the application.*
- *Do not apply the defibrillation paddles in the vicinity of the pacemaker electrodes.*
- *The availability of an external pacemaker is of utmost importance in this case.*
- *After the defibrillation the working order of the implanted pacemaker should be checked immediately.*

Also be aware that children require less energy for a successful defibrillation than adults. For the first defibrillation pulse delivered to babies and toddlers, select an energy level of 2 joules/kg body weight. For subsequent shocks, increase the energy up to 4 joules/kg.

2. Controls and Indicators

This section describes the CardioServ operating controls and indicators and explains their function.

When operating elements in this manual are identified with a reference number in parentheses, this number refers to Figure 2-1 in this section.

You will also find an explanation of all signs and symbols used on the CardioServ defibrillator.

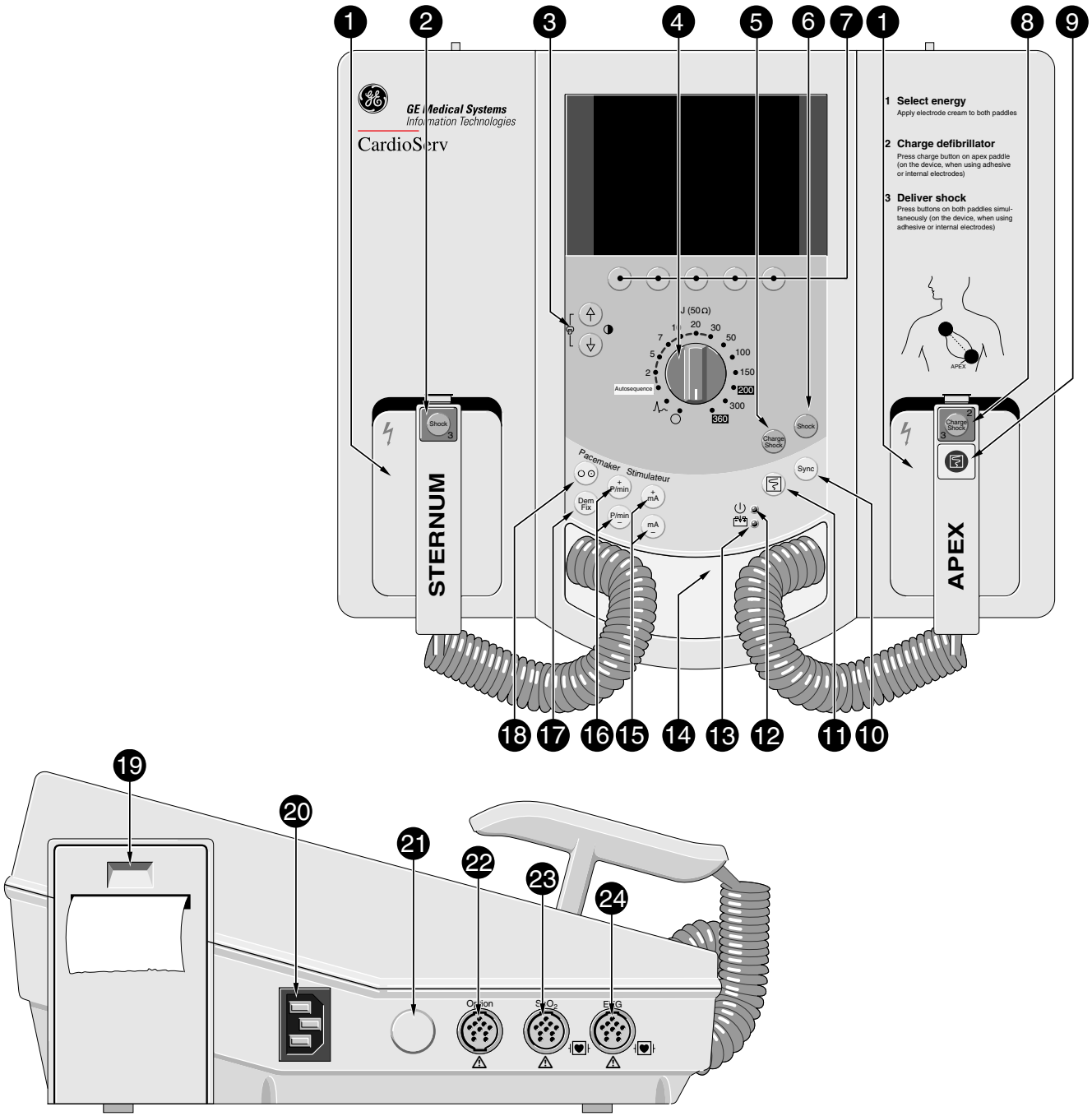

Figure 2-1. Controls and indicators of CardioServ

1 Defibrillator paddles

2 Shock button to trigger the defibrillation shock – together with button (**8**)

3 ↑ ↓ ◑ keys to adjust the LCD contrast. Press both keys simultaneously to obtain a screen copy.

4 Energy selector, on/off switch

5 Charge Shock key to charge the unit (manual mode) and to trigger the defibrillation shock – together with key (**6**). This key assumes the function of button (**8**) when internal paddles or adhesive electrodes are used.

6 Shock key to trigger the defibrillation shock – together with key (**5**). This key assumes the function of button (**2**) when internal paddles or adhesive electrodes are used.

7 Five selection keys **F1 to F5** whose functions change with the menu displayed. The respective key functions are indicated by symbols or labels in the bottom line on the LCD. From the main menu, that appears on power up, you can access submenus which, in turn, allow the selection of further options. The **back** function returns you to the next higher menu level. The main menu reappears automatically if you do not depress any of the keys for about 30 seconds.

8 Charge Shock button to charge the unit (manual mode) and trigger the defibrillation shock – together with button (**2**)

9 button to start and stop the recorder.

10 Sync key to switch to the synchronized operating mode (section 5 “Cardioversion”)

11 key to start and stop the recorder. This key assumes the function of button (**9**) when internal paddles or adhesive electrodes are used.

12 Green indicator ⏻ is lit when the defibrillator operates on line power.

13 Yellow indicator is lit when the defibrillator battery is being charged.

14 Connection for defibrillator paddles

(controls **15** to **18** only on models with pacemaker)

15 Keys + mA mA - to adjust the pacer output

16 Keys + P/min P/min - to adjust pacer rate

17 Pacing mode selection key Dem Fix (demand/fixed rate)

18 Key to enable and disable the pacemaker

19 Aperture to open the paper compartment

20 Connector for power cord

21 Unassigned

22 1-Volt ECG output

23 Connector for SpO_2 sensor

24 Connector for patient cable (ECG signal input)

Explanation of the signs and symbols used on the defibrillator

Type CF equipment with highly insulated patient connections, suitable for intracardiac application, connections defibrillation-proof.

Type CF equipment with highly insulated patient connections, suitable for intracardiac application, connections **not** defibrillation-proof.

Standby mode (for line-power operation)

Power off

Battery charging

Recorder start

ECG signal

Contrast

Direction indicator

Signal output

Audible alarm on/off

High voltage

Standby or preparatory state only for a part of the equipment

On, only for a part of the equipment

Refer to Operator's Manual

Hardcopy of screen image

This symbol indicates that the waste of electrical and electronic equipment must not be disposed as unsorted municipal waste and must be collected separately. Please contact an authorized representative of the manufacturer for information concerning the decommissioning of your equipment.

3. Setting Up CardioServ and Testing Its Performance

In this section you will find information about

- **putting CardioServ into operation**
- **connecting CardioServ to the 12-Volt power supply of an ambulance vehicle**
- **customizing the CardioServ settings to suit your personal requirements**
- **testing the CardioServ performance before using it on a patient**

3.1 Setting Up CardioServ

> ***The defibrillator is a high-voltage electrotherapy device and must be handled by qualified personnel only. Improper use of this device can endanger life. Do not fail to observe the information given in this manual and only entrust the device to the hands of trained persons.***
>
> ***Check the electrodes and their leads for signs of damage every time before you use the defibrillator. In particular, make a close visual inspection of the insulation. Replace internal electrodes or the contact inserts when you detect signs of mechanical damage.***

CardioServ operates on:

– line power (95 to 240 V, 49 to 65 Hz)

– battery power (rechargeable batteries), i.e., independent of the power line

– 12-Volt power supplied from the emergency vehicle (with optional defibrillator mounting system)

* Use the power cord to connect the defibrillator to the power line (Figure 3-1).

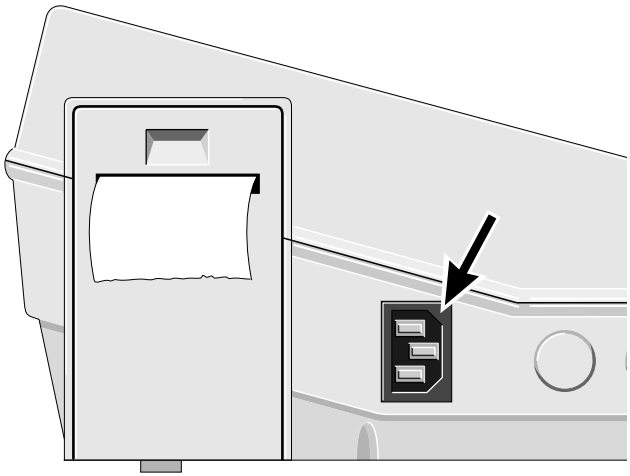

Figure 3-1. Power input

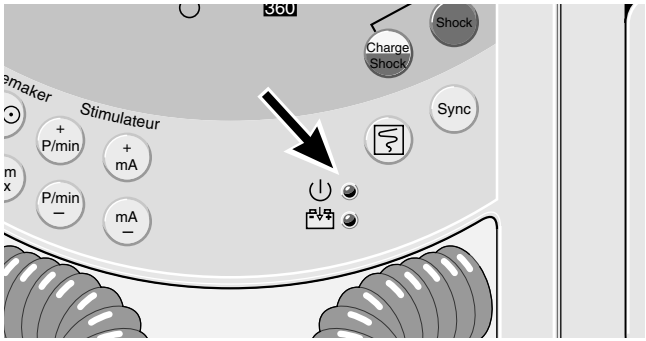

Figure 3-2. Green indicator (indicating that defibrillator is supplied from the power line)

* Check that the green indicator is lit (Figure 3-2).

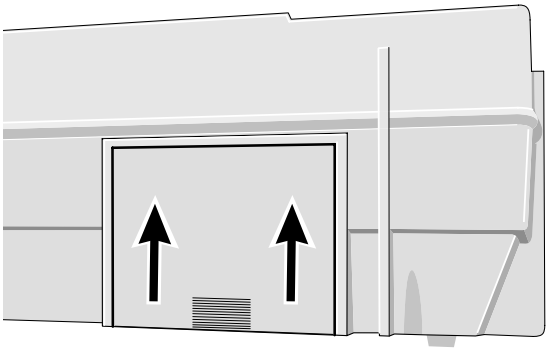

Figure 3-3. Inserting the battery

* Check that the battery is in place (Figure 3-3).

Pull back the catch on the underside of the device to remove the battery. When inserting it, make sure that it clicks properly into place.
When a battery is inserted, the yellow indicator starts flashing as soon as the defibrillator is connected to the power line (to indicate that the battery is charging). The battery is fully charged after 16 hours and the indicator is continuously lit.

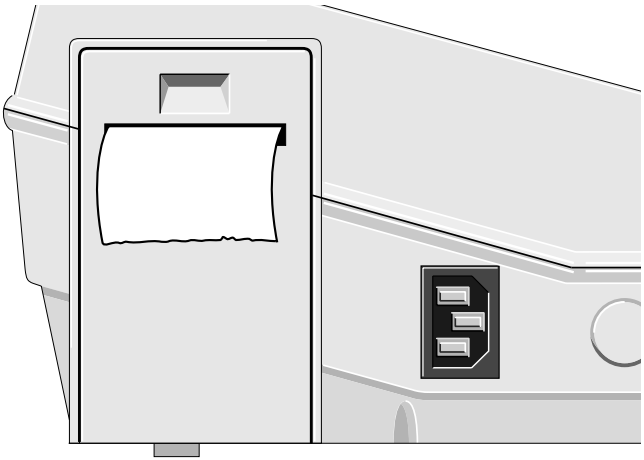

Figure 3-4. Recording strip

* Check that the supply of chart paper is sufficient (Figure 3-4). A stripe marks the last 3 meters of the roll.

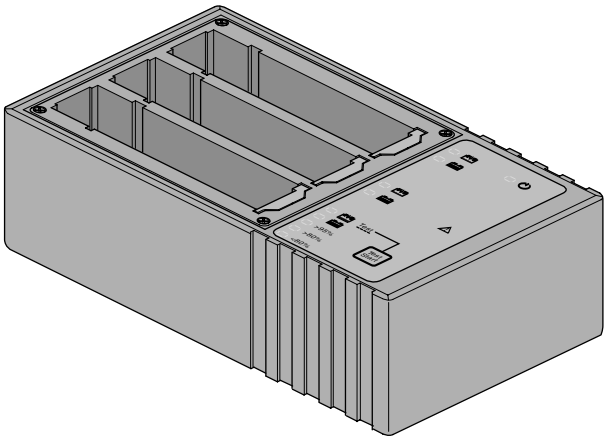

Figure 3-5. Accu Service Unit

☞ ***We recommend our Accu Service Unit for optimal care of the batteries. It prolongs the batteries' service life and guarantees their operational readiness at all times.***

Warning

A NiCd battery should not be charged while located in direct sunlight, over a radiator, in cold storage, or in other temperature extremes (not below 5 °C). When the instrument is charging, ambient temperatures exceeding 40 °C may adversely affect battery capacity and life.

Power Supply From Emergency Vehicles

A qualified technician can be called in to connect the **CardioServ** to the 12-Volt supply of an emergency vehicle. The following points must be noted:

– The negative terminal of the ambulance power supply system must be connected to the ambulance chassis for grounding.

– The positive lead of the ambulance power supply system intended to supply the current must be protected with a 10-A fuse.

– Use only the defibrillator mounting system listed in section 15 "Order Information and Accessories" or the external charging unit, if your **CardioServ** has been modified accordingly.

⚠ Check that the contacts for power supply from the defibrillator mounting system on the underside of **CardioServ** (next to battery) are clean. Do not damage them in any way.

Important Information on Battery-Power Operation

Rechargeable batteries require special maintenance and continued checks to assure they function in emergency situations. It is normal for batteries of this type to selfdischarge when not in use.

The battery charges automatically when **CardioServ** is connected to the power line (yellow indicator (**13**) flashes).

In order to ensure its functioning as an emergency device, the defibrillator should not be disconnected from the power line for more than 48 hours.

A fully charged battery supplies power for 35 defibrillation shocks of 360 joules or 2 hours of monitoring (or 1.2 hours of monitoring if the **CardioServ** unit has pacemaker and SpO_2 option). It takes 16 hours to charge a depleted battery.

☞ *Proceed as follows to test the battery charge level:*

- *Disconnect CardioServ from the power line.*
- *Trigger a test discharge of 360 joules (see section 3.2 "Testing the Defibrillator Performance").*
- *If you are not prompted to charge the battery, the charge level should be sufficient for at least 5 more 360-joule shocks.*

☞ *Monthly battery maintenance and checks:*

1. *Disconnect CardioServ from the power line and discharge fully charged battery in the monitoring mode. To do so, set energy selector switch to* *, (SpO_2 sensor not connected) and wait until device switches off.*
2. *Check how long it takes before battery is depleted. If the time is less than 1.8 hours, the battery is too old or improperly maintained and must be replaced.*
3. *Recharge the battery. This will take 16 hours.*

For easy, convenient care and maintenance of the batteries, use our "Accu Service Unit".

Inserting CardioServ In Its Softcase

* Open both zips on the CardioServ softcase.
* Undo the two Velcro strips on the front of the softcase.
* Open the Velcro flap located in front of the CardioServ printer.
* Place the softcase on the small base, so that the softcase is positioned as though you were carrying it.
* Disconnect the paddles on the CardioServ and remove them.
* Hold all the opened up parts of the softcase to the side and put the CardioServ into the softcase.
* Pull the softcase by the two Velcro strips on the black base into position, ensuring that the feet of the CardioServ are in the cut-out openings provided.
* Close the two front Velcro strips as well as the flap in front of the printer at the side.
* Close the zips.
* If the individual cut-out openings for the external connections, paddles or feet are not correctly positioned, pull the material at this point into the right shape.
* Reconnect the paddles and put them back into the CardioServ recesses.

Customizing the defibrillator settings

Further steps that can be taken while setting up the defibrillator include customizing the device functions. This allows you to select defibrillator default settings which suit your personal preferences. **CardioServ** saves these configured settings and reactivates them automatically every time you switch the defibrillator on. The following chart shows the factory settings of all parameters and the optional adjustments.

Refer to section 11 “The Defaults Menu” for a detailed explanation of how to customize the **CardioServ**, including the language selection (available languages are English, French, German, Italian, Portuguese, Russian, Spanish and Swedish).

Parameter	Description	Factory Setting	Adjustment range	Customized settings
HR Limits	HR alarm limits	40/160	off 15 to 300 off	
Sensitivity	ECGsignal size	1	.5, 1, 2 cm/mV	
Lead		1	all standard leads + paddles	
Autoseq.	autosequencing energy levels	200 J, 200 J, 360 J	150 J, 200 J, 300 J, 360 J,	
SpO_2 Limits	alarm limits	90/off	off 15 to 100 off	
C-Lock	ECG-synchronized SpO_2 measurement	off	on/off	
SpO_2 Int. Time	SpO_2 integration time	8 s	4 s, 8 s, 12 s (not recommended)	
Lead Fail Alarm		off	off / 30 s	
QRS Beep		off	on/off	
Alarm Tone		off	on/off	
Alarm Printout	autom. recorder start	off	on/off	
Shock Printout	autom. recorder start	on	on/off	
Cont. Printout	recorder stop upon manual start	off	on/off	
Pacemaker	pulse rate	60 BPM	15 to 150 P/min	
Display		normal	normal/reversed	
Display		0 degrees	0 degrees/180 degrees	
Volume	volume of all audio signals	loud	loud/low	
AC Filter		50 Hz	50 Hz / 60 Hz / off	
Muscle Filter	elimination of motion artifact	on	on/off	
Date/Time				
Date Format		DD:MM:YYYY	DD:MM:YYYY/MM:DD:YYYY	
Language		German	English, French, German, Italian, Portuguese, Russian, Spanish, Swedish	
User	free text or name (40 characters)			
Factory default	reestablish factory settings	off	on/off	

Table 1

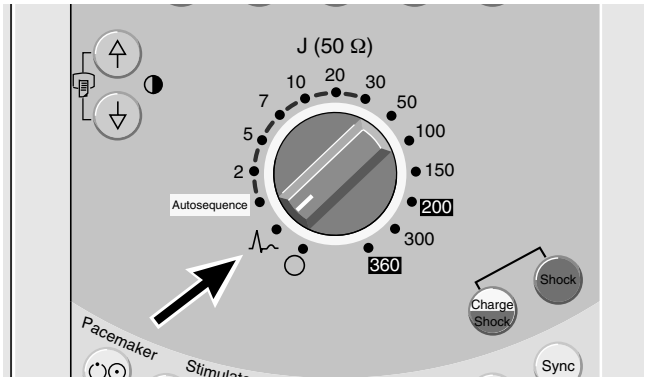

Figure 3-6. Switching on CardioServ

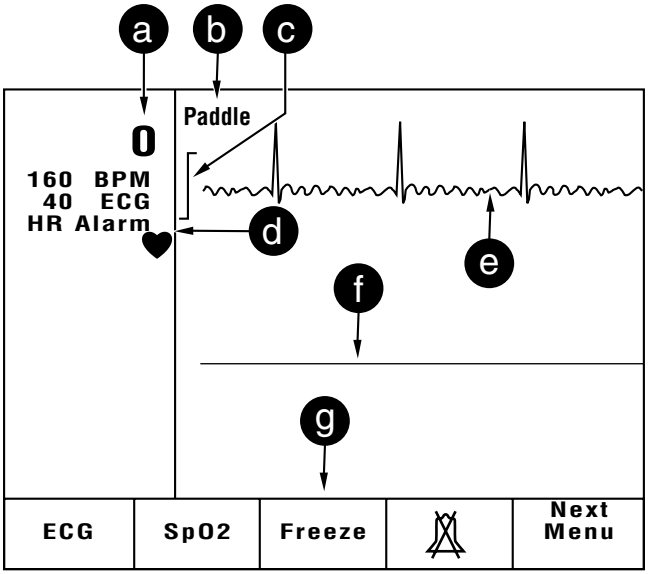

Figure 3-7. CardioServ main display

- *a heart/pulse-rate reading with alarm limits*
- *b ECG signal source*
- *c 1-mV calibration pulse*
- *d alarm message, QRS blip*
- *e signal trace, channel 1*
- *f signal trace, channel 2*
- *g menu*

3.2 Testing the Defibrillator Performance

On power up **CardioServ** runs an automatic selftest. Any malfunctions identified during this test result in an error message displayed on the LCD (refer to section 12 "Error Indications and Messages"). As a further performance test a trial defibrillation can be triggered.

The energy selector is used to switch **CardioServ** on and off. Once you have become familiar with **CardioServ** you can thus switch on the defibrillator and select the required energy in one single operation.

* Set the energy selector to the position. No energy will be stored in this position of the switch.

The defibrillator beeps and displays a checkered pattern (LCD performance test). Next the main display appears (Figure 3-7).

The "Paddle" message (**b**, Figure 3-7) indicates that no patient cable is connected and that the ECG signal is acquired via the defib paddles. Upon connection of the patient cable the selected ECG lead is displayed here. **CardioServ** is now ready for operation.

> ***Caution*** *Do not trigger more than 5 consecutive test discharges (or internal safety discharges) within 15 minutes at max. energy setting.*

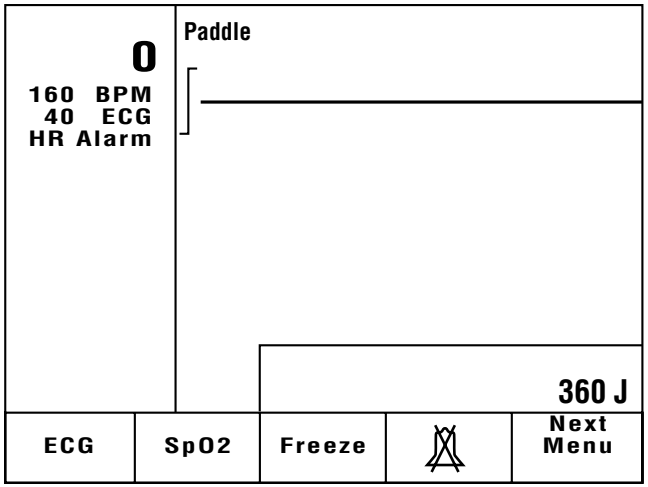

Figure 3-8. Display of selected energy

> ***Caution*** *Do not deliver shocks into open air. High voltage may briefly be present at the unprotected paddle surfaces as a result and endanger the persons present.*

Test Discharge

A test discharge can be triggered to check the defibrillator discharge circuit. For this test the stored energy is discharged into the device via two contacts in the paddle compartments.

* Set the energy selector to 360 joules (50 joules, if internal electrodes are connected). The display first shows the selected energy (Figure 3-8).

* Press the Charge/Shock button on the paddle to charge the unit. (Press the Charge/Shock key on the defibrillator, when using internal electrodes.)

You may now watch the defibrillator charging.

* When the selected energy level has been reached, **CardioServ** beeps and the stored energy is displayed (Figure 3-9).

* Trigger the defibrillation pulse within the next 30 seconds. To do so, simultaneously press the buttons on both paddles (or press the two Charge/Shock Shock keys on the defibrillator, when using internal electrodes).

If more than 5% of the available energy are lost before the defibrillation pulse is triggered, **CardioServ** recharges until the required energy level is reached.

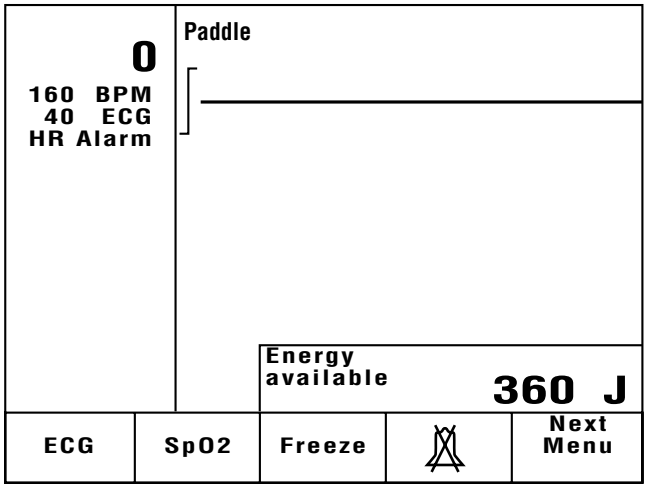

Figure 3-9. Display of available energy

☞ *If you do not trigger the defibrillation pulse within 30 seconds, an internal safety discharge is initiated automatically.*

Caution

The message "Energy high" or "Energy low" indicates that CardioServ needs to be repaired. If, in spite of this energy storage problem, the device has to be employed, it will display the message "Self-test failed. Charge Energy Error" upon power up. In this situation press one of the function keys and proceed as usual.

After defibrillation, the beeping sound stops, and the energy actually delivered into a 50-ohm resistance is displayed for 10 seconds in place of the stored energy (Figure 3-9). The delivered energy must not deviate more than ±15% or ±4 joules (whichever is greater) from the selected value. A recording is initiated at the same time (16-second strip).

Should the discharge circuit be interrupted (paddles not properly placed on contacts in the compartments, defective lead), an internal safety discharge is initiated 200 ms after the defibrillation shock has been triggered. In this case the "delivered energy" is "0".

If the defibrillator cannot store the selected energy so that selected and stored energy values differ, the LCD shows the message "Energy high" or "Energy low". The defibrillation pulse can be triggeed all the same.

* Switch off **CardioServ** (set energy selector to ◯).

Testing the Pacemaker Performance

The performance of the pacemaker can be tested with a commercially available pacemaker tester (e.g. CS300 Simulator from GEMS IT, part no. 417 983-001).

Caution

Performance Test

Test the defibrillator performance once a week:
test 1 – defibrillator connected to mains, battery removed,
test 2 – defibrillator disconnected from mains, battery inserted

For your notes

4. Non-Synchronized Defibrillation

This section describes first how to perform a non-synchronized defibrillation, using the standard defibrillation paddles. The subsequent explanations refer to the use of internal and disposable adhesive electrodes.

At the end of this section you will find a summary of all necessary operating steps (brief operating instructions).

4.1 Defibrillation with Standard Electrodes

> ***The information given in section 1.2 must be observed without fail to ensure safe and reliable application of the device.***
>
> Warning

> ***Always switch off CardioServ before exchanging the defibrillation paddles.***
>
> Danger

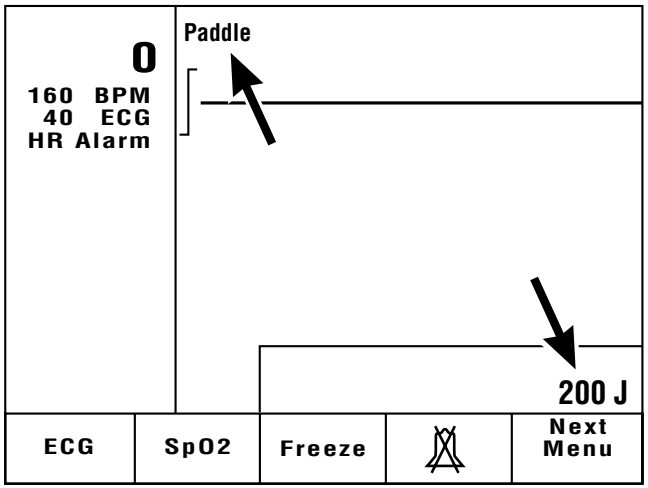

Figure 4-1. Main display, indication of ECG lead, manual operation and selected energy

The energy selector can be set to the autosequence position, where the defibrillator automatically sequences the preset energy levels. The preset factory default setting is the sequence recommended by AHA/ERC (200 J, 200 J, 360 J). The factory default values can be changed from the defaults menu. You can choose among 150 J, 200 J, 300 J and 360 J.

* Set the energy selector (4) to "Autosequence" or to the required energy value (this turns on **CardioServ**).

The defibrillator beeps and displays a checkered pattern (LCD performance test). Next the main display appears (Figure 4-1). When a patient cable is connected the selected ECG lead is displayed (selectable).

* Check that the energy selector locks in on the correct position and that the display shows the selected energy (Figure 4-1).

The energy depends on the defibrillation mode, on the patient's age and constitution. In external application the thickness of the tissue is also a factor which influences the amount of energy required.

The energy necessary for successful ventricular defibrillation without damaging the myocardium has for many years been a matter of scientific controversy. The manufacturer is therefore not able to give any recommendations.

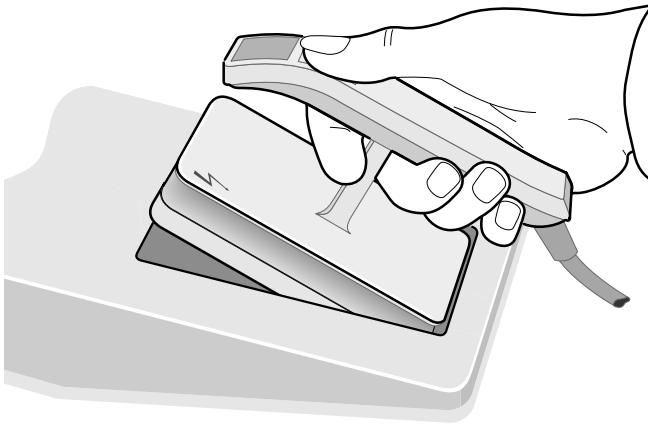

Figure 4-2. Removing the paddles

> **Warning**
>
> ***Do not apply the paddles over***
> – ***sternum or clavicle***
> – ***nipples***
> – ***implanted pacemaker or defibrillator.***

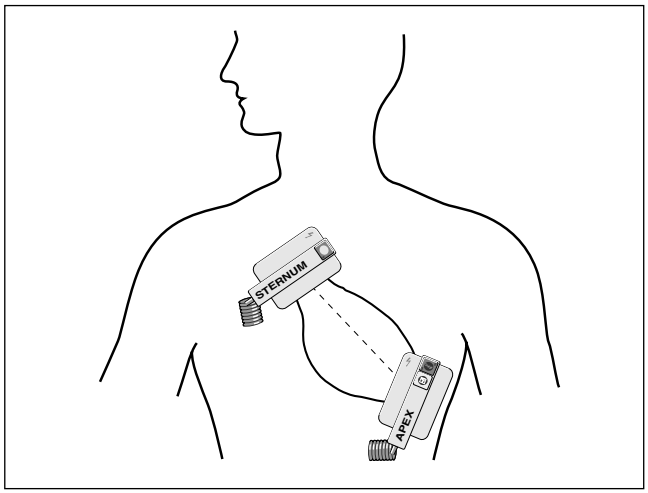

Figure 4-3. Paddle application points

In emergency situations AHA recommends for adult patients

1. defibrillation with 200 joules; if unsuccessful, repeat

2. defibrillation with 200 joules; if unsuccessful, repeat

3. defibrillation with max. energy setting (360 joules).

Please note that children require less energy for successful ventricular defibrillation than adults. For the first defibrillation pulse delivered to babies and small children, select an energy level of 2 joules/kg body weight. For subsequent shocks, the energy may be increased to 4 joules/kg.

In compliance with IEC requirements the energy adjusted on this defibrillator is not the stored energy, but the energy released into an external resistance of 50 ohms (patient resistance + electrode-to-skin contact resistance). The energy selector is labelled accordingly.

* Remove the paddles from their compartments (as shown in Figure 4-2). Carefully dry the electrodes, if they are wet. The handles, in particular, must be completely dry. Apply an ample amount of electrode cream to each paddle.

* Apply the electrodes to the patient's thorax so that the greatest possible amount of energy flows through the myocardium (the imaginary connecting line between the two electrode centers should be identical with the cardiac median line; Figure 4-3).

* Press paddles firmly down onto the patient's thorax..

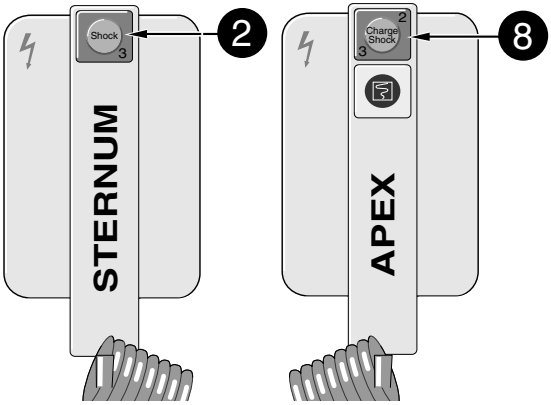

Figure 4-4. Buttons to initiate energy storage and to trigger the defibrillation shock

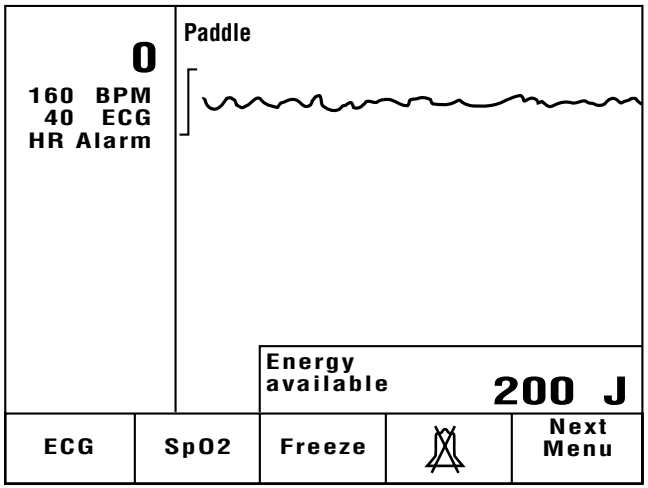

Figure 4-5. Display of available energy

> ☞ ***When the defibrillator is already charged you can increase the energy level simply by turning the energy selector to the new setting. To decrease the energy level, set the selector to the lower value and initiate charging again.***

The ECG signal trace appears on the monitor.

* Do not touch the patient any more and warn all those present.

* Press the Charge Shock button (8) on the apex paddle to initiate charging (Figure 4-4). When using internal electrodes or defibrillation pads, press Charge Shock on the device.

When the selected energy level has been reached (message "Energy available"), **CardioServ** beeps and the stored energy is displayed (Figure 4-5).

* Trigger the defibrillation shock within the next 30 seconds by simultaneously pressing the buttons on both paddles (Figure 4-4). When using internal electrodes or defibrillation pads, press Charge Shock and Shock on the device.

If more than 5% of the available energy are lost before the defibrillation shock is triggered, CardioServ recharges until the required energy level is reached.

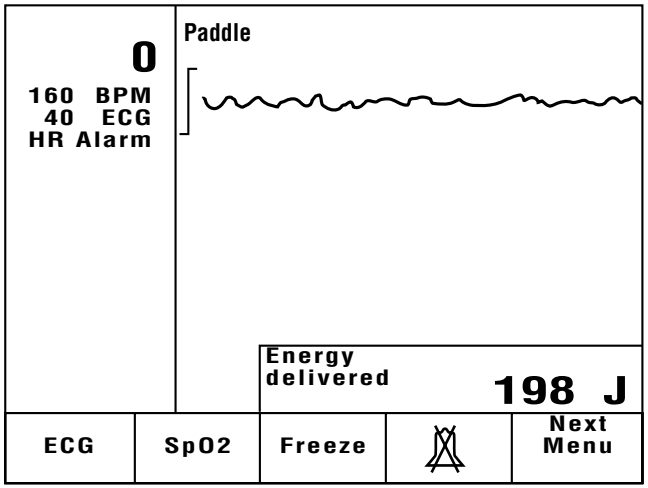

Figure 4-6. Display of delivered energy

☞ ***The "Check Electrode" message refers to the defibrillation paddles only when no patient cable is connected. It refers to the ECG electrodes when the patient cable is plugged in.***

☞ ***If you do not trigger the defibrillation pulse within 30 seconds, an internal safety discharge is initiated automatically. You will then have to recharge the defibrillator.***

Warning

The defibrillation energy (high voltage!) remains applied to the defibrillation paddles until fully discharged. Do not touch the paddle surface! The internal safety discharge is completed when the selected energy is displayed again.

– After defibrillation, the beeping sound stops, and the energy actually delivered is displayed for 10 seconds in place of the stored energy (Figure 4-6). At the same time the recorder writes a 16-second ECG (including a history of 4 seconds) (adjustable, Figure 4-7). **CardioServ** saves this recording (4 s history, 5 s blanked, 10 s after release of shock), and it can be printed off again at any time. Also refer to section 7 "The Memories of CardioServ".

– When the electrodes are not applied at all or they are not properly applied to the skin, the message "Check Electrode" is displayed. The defibrillation shock can be triggered all the same. Nevertheless it is recommended to reduce skin impedance (risk of skin burns!), for instance, by applying more electrode cream to the paddles or by pressing them down firmly.

– When there is a break in the discharge circuit (paddles not properly applied, leads or paddles defective), an internal safety discharge is initiated 200 ms after the defibrillation shock has been triggered. In this case the "delivered energy" is "0".

– If the defibrillator cannot store the selected energy so that selected and stored energy values differ, the LCD displays a warning. The defibrillation pulse can be triggered anyway (notify service).

* Once therapy has ended, set the selector switch to for monitoring of the patient's ECG.

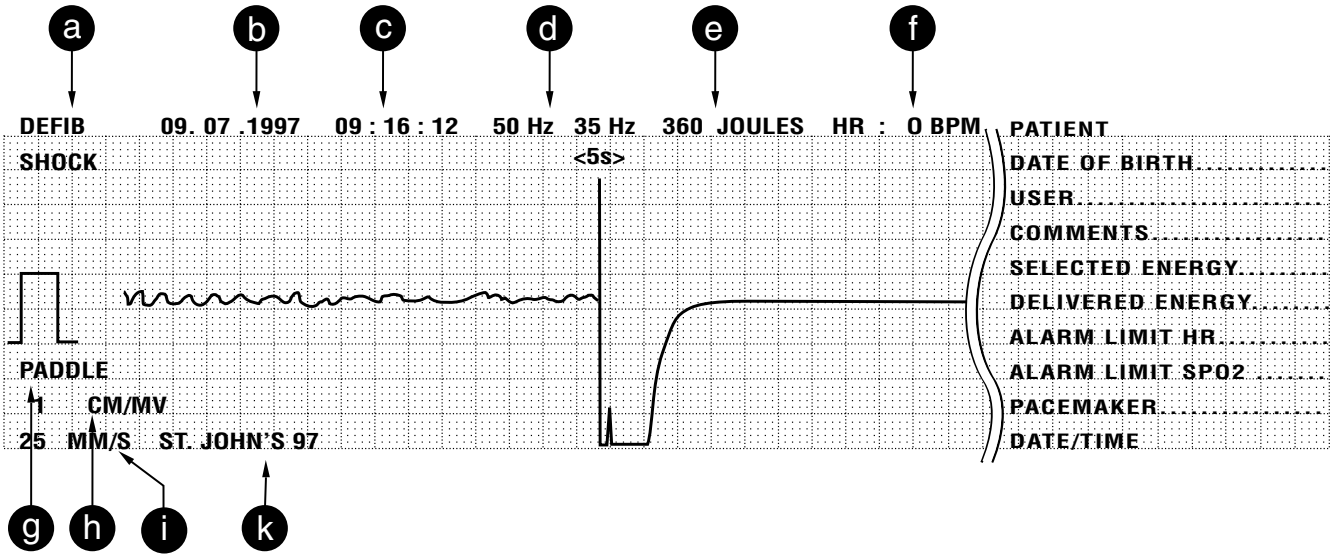

Figure 4-7. Example of a recording initiated by a defibrillation pulse

a initiation
b date
c time
d active filters
e delivered energy
f heart rate
g ECG lead
h sensitivity
i paper speed
k name of hospital/practise

* After use, switch off **CardioServ** (set selector switch to ◯).
* Clean the paddles and the device as described in section 13.
* After cleaning, return the paddles to their compartments as shown in Figure 4-8.

Figure 4-8. Returning the paddles to their compartments

4.2 Defibrillation with Internal Electrodes or Single-Use Pads

Internal Electrodes

> ☞ *When using CardioServ with internal or adhesive electrodes, charging is initiated with Charge/Shock and defibrillation is triggered by simultaneously pressing the Charge/Shock and Shock (Figure 4-9). Only sterile electrodes may be used for internal defibrillation!*

When electrodes for internal defibrillation are connected to **CardioServ**, it is not posssible to store energy above 50 joules. If you set the selector to values higher than 50 joules, release of the defibrillation pulse is blocked for reasons of patient safety ("Energy high" will be displayed!). Simply turn the dial back and initiate charging again, this time selecting not more than 50 joules.

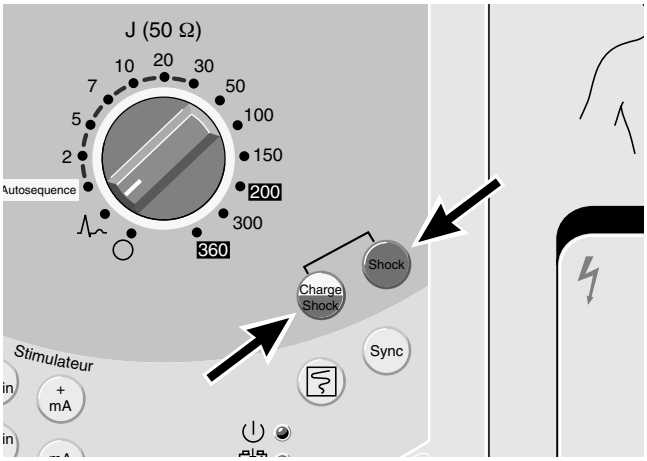

Figure 4-9. Panel keys to initiate charging and to trigger the defibrillation shock

Spoon-shaped electrodes are used for internal defibrillation. Their contact surface must match the dimensions of the heart, as the spoons should make full contact with the tissue.

You can choose from 3 different spoon sizes (section 15 "Order Information, Accessories"). As the spoons are in direct contact with the heart – hence the term "direct defibrillation" – energy levels considerably lower than those for transthoracic (external) defibrillation are sufficient.

Please note that internal electrodes must be sterilized before use (section 13 "Cleaning and Disinfection").

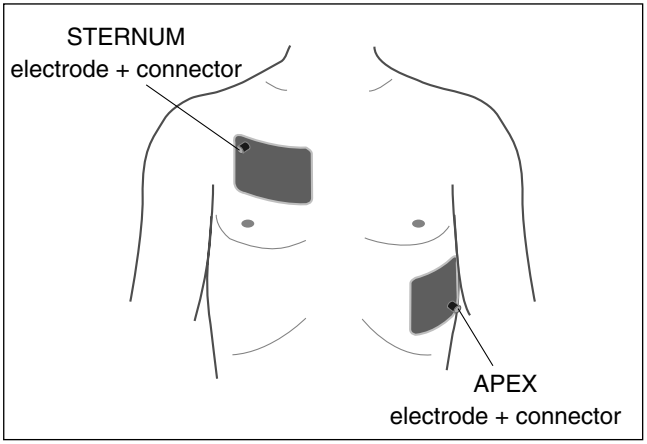

Figure 4-10. Anterior – anterior placement

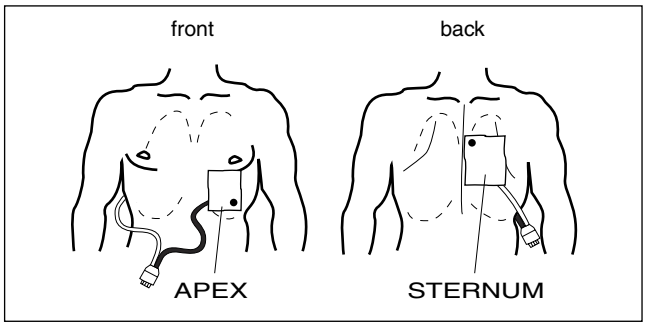

Figure 4-11. Anterior – posterior placement

Single-Use Defibrillation Pads

* Use pads before their expiration date.

* A pair of defibrillation pads may remain attached to the patient for up to 24 hours. They withstand up to 50 shocks of 360 joules each.

* Apply the pads (part no. 919 202 94 adult pads, part no. 919 202 95 pediatric pads) as shown in Figure 4-10 for an anterior-anterior placement, and as shown in Figure 4-11 for an anterior-posterior placement:

  – Shave any hair from each site. This improves conductivity and makes removal of the pad easier.

  – Place the pads on the patient so that the connectors point to either side of the patient. In this position the connecting cables will not hinder CPR measures.

  – The electrodes are pregelled; therefore do not use additional contact cream or paste.

  – Do not use pads, if the gel has dried out.

  – Peel off the backing from each pad and place the pad carefully on the appropriate site.

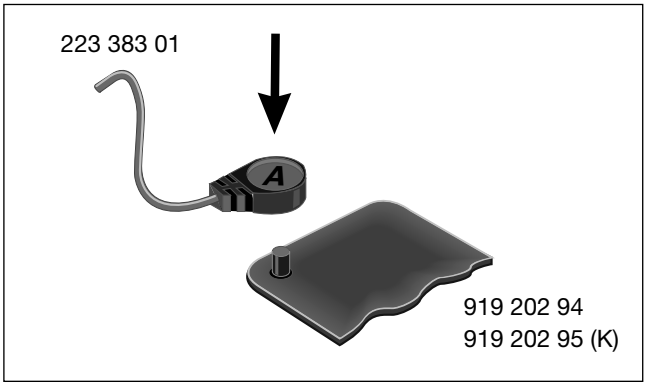

Figure 4-12. Connecting the cables

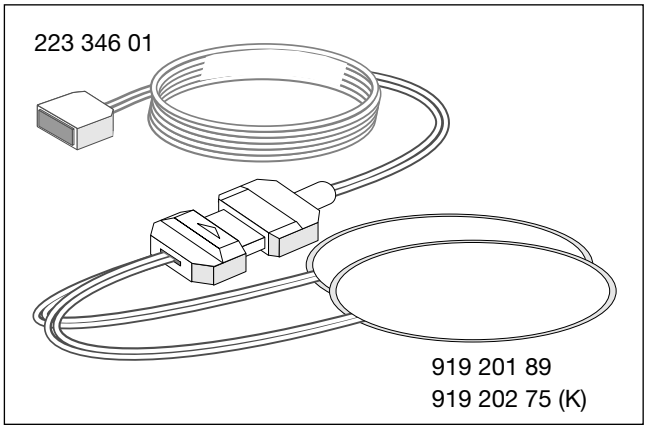

Figure 4-13. Connecting the defib pads to the adapter cable

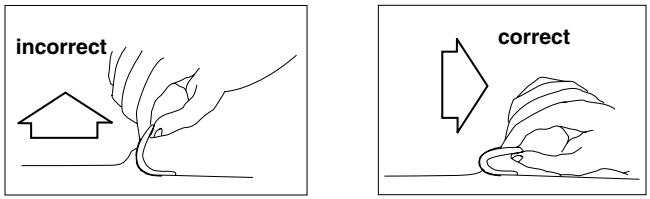

Figure 4-14. Removing defibrillation pads

* Then press the connector of cable 223 383 01 on to the electrode contact pin until you hear it click into place. Observe the connector lables: “A” = apex, “S” = sternum.

The round adhesive electrodes (part no. 919 201 89) can be used with adapter lead 223 346 01. When connecting the electrode to the lead, take care that they engage properly. To disconnect them, simply press on the rear part of the catch (Figure 4-13).

* Before defibrillating the patient, verify the position and adhesion of the pads.

* Defibrillate the patient as described in section “Defibrillation with Standard Electrodes”. Note, however, that energy storage and defibrillation pulse will have to be triggered with the panel keys.

* After use, carefully peel off the electrodes from the patient’s skin (Figure 4-14) and discard them immediately.

Warning *When monitoring the patient with the adhesive defib pads, make sure that the energy selector is in the monitoring position .*

Warning *Discard disposable defibrillation pads immediately after use. Do no reuse them!*

4.3 Brief Operating Instructions (non-synchronized)

External Electrodes/Paddles

* Set energy selector to “Autosequence” or select the required energy (1)
* Remove paddles from compartments and apply electrode cream
* Apply electrodes to thorax
* Initiate defibrillator charging (2)
* Wait for beep to sound and for stored energy to be displayed
* Warn bystanders, do not touch the patient any more and trigger shock; to do this, simultaneously press on both paddles (3)
* Watch ECG, repeat defibrillation if necessary or set energy selector to , if defibrillation was successful
* Switch off **CardioServ** after use (set energy selector to ◯)
* Clean paddles and defibrillator

Internal Electrodes or Pads

* Connect internal electrodes or pads to **CardioServ**
* Apply pads
* Set energy selector to “Autosequence” or select the required energy (**50 joules max. for internal defibrillation**) (1)
* Initiate defibrillator charging (2)
* Wait for beep to sound and for stored energy to be displayed
* Warn bystanders, do not touch the patient any more and trigger shock; to do this, simultaneously press the keys on the panel (3)
* Watch ECG, repeat defibrillation if necessary or set energy selector to , if defibrillation was successful
* Switch off **CardioServ** after use (set energy selector to ◯)
* Dispose of single-use electrodes, clean defibrillator
* Clean/sterilize internal electrodes

5. Cardioversion (Synchronized Defibrillation)

This section describes first how to perform a synchronized defibrillation (cardioversion). For this purpose, the ECG is picked up either via the paddles or via separate ECG electrodes.

At the end of this section you will find a summary of all necessary operating steps (brief operating instructions).

5.1 General Information

For cardioversion, the defibrillation shock is delivered in synchronization with the heart action (on the R-wave), as the heart is still working. As a prerequisite the patient's ECG signal must be supplied to the defibrillator. After the defibrillator has received the "defibrillation command" from the operator who pressed the appropriate keys, the defibrillator will wait for the next R-wave to derive the trigger signal.

It is strongly recommended to acquire the ECG via separate ECG electrodes. However, you may also use adhesive defibrillation pads and simultaneously acquire the ECG via these pads.

Warning

The information given in section 1.2 must be observed without fail to ensure safe and reliable application of the device. Also read section 6.1 "Displaying the ECG".

Warning

False Triggering – If ventricular fibrillation occurs during the intervention, you must switch to the non-synchronized mode to be able to trigger a defibrillation pulse, because it is not possible to detect a QRS complex in the presence of ventricular fibrillation and the QRS complex is necessary to derive the trigger pulse.
Do not use a pacemaker ECG for triggering, because the trigger pulses derived from pacemaker ECGs may be incorrect and synchronized delivery of the defibrillation shock may not be possible.

☞ ***Following each synchronized defibrillation, CardioServ reverts to the non-synchronized mode. Please note that the synchronized mode must be deliberately activated with*** Sync ***every time you want to perform cardioversion. This measure is to ensure that in emergencies the defibrillator is always ready to deliver nonsynchronized shocks.***

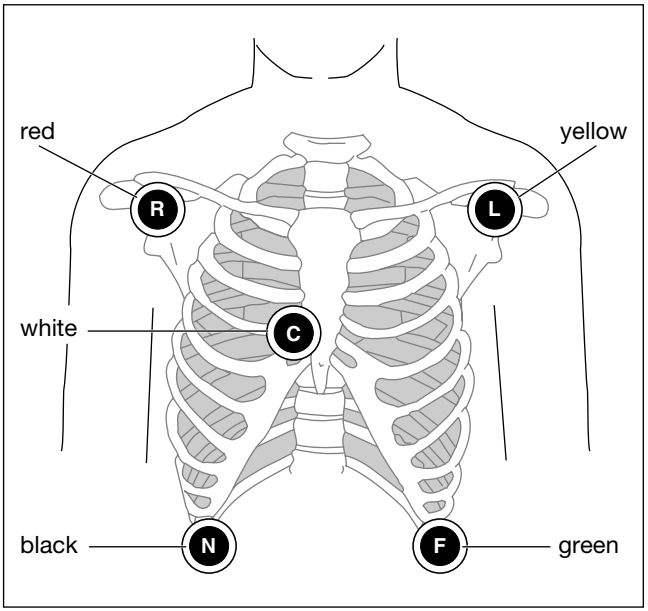

Figure 5-1. ECG electrode placement

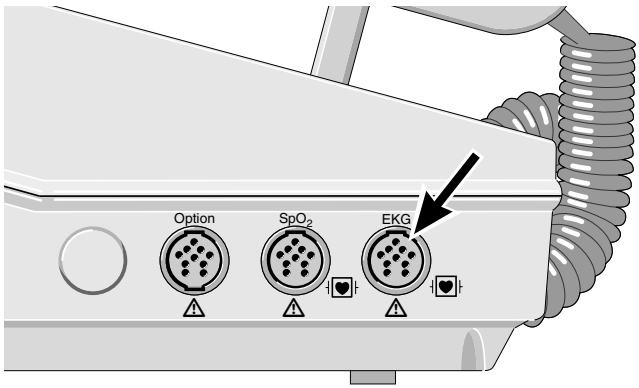

Figure 5-2. ECG signal input

5.2 Performing Cardioversion

ECG Acquisition via ECG Electrodes and Patient Cable

Use only siver/silver chloride electrodes if you intend to acquire the ECG signal via the patient cable. This type of electrodes prevents polarization voltages which may be caused by the defibrillation shock, resulting in an ECG trace simulating cardiac arrest.

* Apply the electrodes as shown in Figure 5-1 and connect them to **CardioServ** via the patient cable (Figure 5-2).

For further information on ECG signal acquisition, please refer to our application note on electrocardiography and to the relevant literature.

ECG Acquisition via Defibrillation Pads

* Apply the pads as described in section 4.2.

* Check that **no patient cable** is connected to ECG signal input (Figure 5-2).

The ECG will now be acquired via the defibrillation pads. Perform cardioversion as described below.

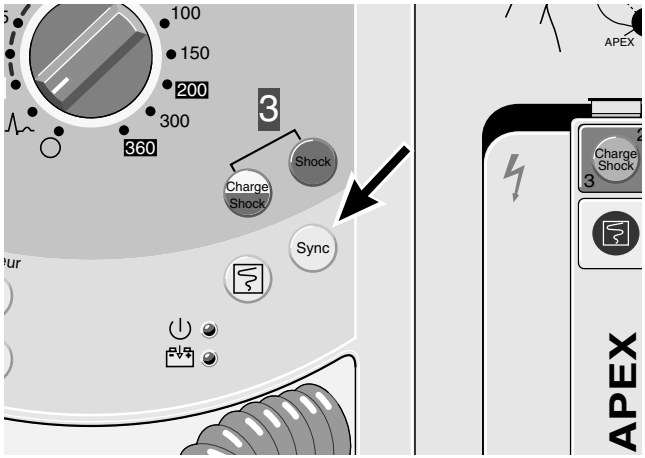

Figure 5-3. Key to select synchronized defibrillation

Cardioversion

* Set the energy selector to ⎍ (this turns on **CardioServ**) and check the ECG trace.

The defibrillator beeps and displays a checkered pattern (LCD performance test). Next the main display and the label of the selected lead are shown (when patient cable is connected). **CardioServ** is now ready for operation.

The defibrillator selects the following settings:

– lead I (selectable)
– AC line filter on (selectable)
– sensitivity of 1 mV/cm (selectable)

If you wish to select another lead or sensitivity, proceed as follows (these are only temporary changes which will not be saved):

* Press the ECG softkey to call up the ECG submenu.

* Use the I...III aV...V Paddle softkey to select a suitable ECG lead (shown at **a**, Figure 5-4).

* Use the 1 cm/mV softkey to select the sensitivity.

* Press Sync (Figure 5-3).

The "Sync" mode is indicated on the LCD (**c**, Figure 5-4).

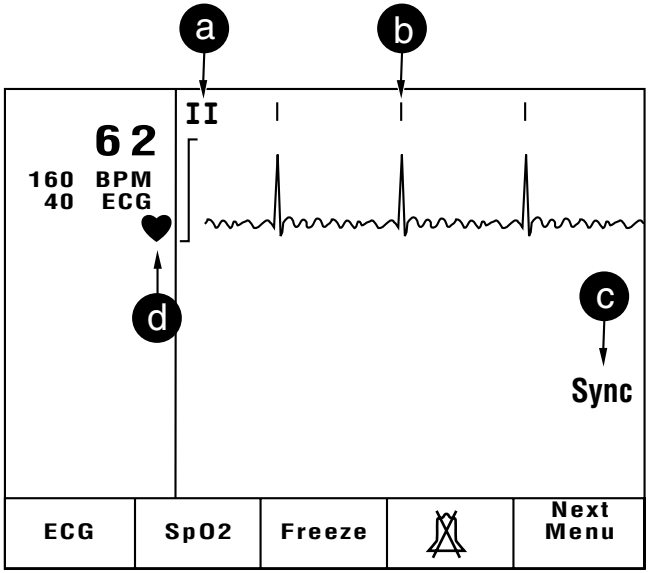

Figure 5-4. Screen display

a selected lead
b Sync mark
c Sync mode on
d heart symbol

☞ ***On the recording strip each sync pulse is identified with a dash above and below the ECG trace.***

If no SYNC marks are displayed, do not trigger a defibrillation shock, because the shock might be delivered unsynchronized with the QRS complexes.

Verify that the heart symbol flashes regularly on the LCD and that the sync mark appears at regular intervals along the upper LCD margin (**b**, Figure 5-4). Otherwise select another lead using softkey [I...III aV...V Paddle] of the ECG submenu.

It is important that the ECG exhibit the following characteristics

– the R-wave amplitude should be greater than 0.5 mV, 1 mV or more are recommended
– the T-wave amplitude should be small in relation to the R-wave amplitude
– the SYNC mark should be located above the leading edge or peak of the R-wave

When the synchronized defibrillation mode is selected, each QRS complex is identified with a SYNC mark (**b**, Figure 5-4). If these SYNC marks are missing, synchronized defibrillation will not be possible. Reasons for missing SYNC marks include poor ECG signal quality. Select another ECG lead, check electrode contact or disable and re-enable the SYNC mode.

For an accurate estimation of the phase in which the defibrillation shock will occur, you can mark the latest point in time on the printed ECG: the defibrillation shock will be triggered not later than 60 ms after the SYNC mark.

* Remove the paddles from their compartments. Carefully dry the electrodes, if they are wet. The handles, in particular, must be completely dry. Apply an ample amount of electrode cream to each paddle.

* Set the energy selector to the required energy level ("Autosequence" is not suitable for cardioversion).

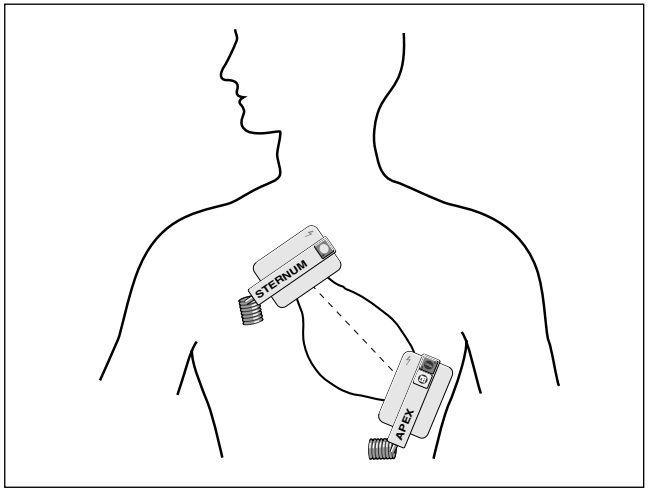

Figure 5-5. Paddle placement

> ***Do not apply the paddles over***
> – ***sternum or clavicle***
> – ***nipples***
> – ***implanted pacemaker or defibrillator.***

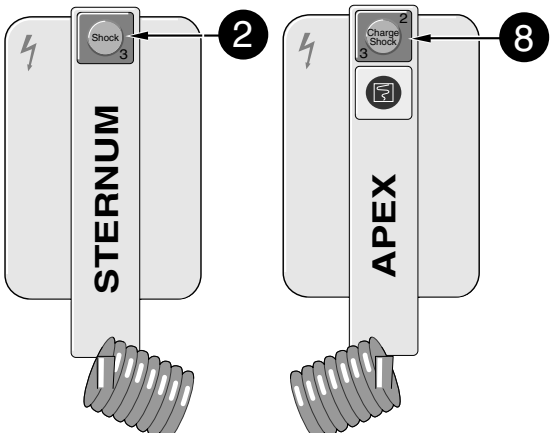

Figure 5-6. Buttons to inititate energy storage and to trigger the defibrillation shock

The energy depends on the defibrillation mode, on the patient's age and constitution. In external application the thickness of the tissue is also a factor which influences the amount of energy required.

The energy necessary for successful ventricular defibrillation without damaging the myocardium has for many years been a matter of scientific controversy. The manufacturer is therefore not able to give any recommendations.

> ***The American Heart Asociation AHA recommends the following energy levels for cardioversion: 50 J, 100 J, 200 J, 300 j, 360 J.***

* Apply the electrodes to the patient's thorax so that the greatest possible amount of energy flows through the myocardium (the imaginary connecting line between the two electrode centers should be identical with the cardiac median line; Figure 5-5).

* Press paddles firmly down onto the patient's thorax.

* Do not touch the patient any more and warn all those present.

* Press the Charge Shock button (**8**) on the apex paddle to initiate charging (Figure 5-6). When using defibrillation pads, press the Charge Shock key on the **CardioServ** control panel.

When the selected energy level has been reached, **CardioServ** beeps and the stored energy is displayed (Figure 5-7). It should be identical with the selected value (±15% or ±4 joules, whichever is greater)

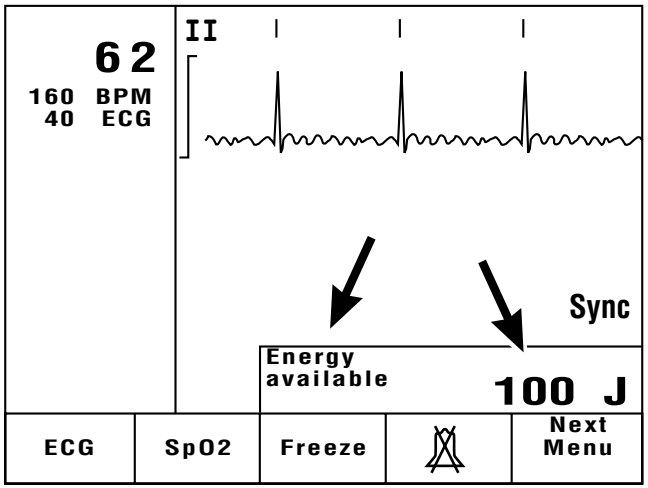

Figure 5-7. Display of the stored energy

☞ ***The "Check Electrode" message refers to the defibrillation paddles only when no patient cable is connected. It refers to ECG electrodes when the patient cable is plugged in.***

Warning ***The defibrillation energy (high voltage!) remains applied to the defibrillation paddles until fully discharged. Do not touch the paddle surface! The internal safety discharge is completed when the selected energy is displayed again.***

* Simultaneously press the butttons on both paddles (Figure 5-6) within 30 seconds. The next synchronization pulse will release the defibrillation shock. When using internal electrodes, press the panel keys Charge Shock and Shock to deliver the shock.

– After defibrillation, the defibrillator stops beeping, and the energy actually delivered to the patient is displayed for 10 seconds in place of the stored energy. At the same time the recorder writes a 16-second ECG, including a history of 4 seconds (adjustable, Figure 5-8). **CardioServ** saves the ECG (4-s history, 5 s blanked, 10 s after release of shock). On the recording the blanked period of time is marked with a spike (Figure 5-8). Refer to section 7 "The Memories of CardioServ".

– When the electrodes are not applied at all or they are not properly applied to the skin, the message "Check Electrode" is displayed. The defibrillation pulse can be triggered all the same. Nevertheless it is recommended to reduce skin impedance, for instance, by applying more electrode cream to the paddles or by pressing them down firmly.

– When there is a break in the discharge circuit (paddles not properly applied, leads or paddles defective), an internal safety discharge is initiated 200 ms after the defibrillation shock has been triggered. In this case the delivered energy is not indicated.

– If the defibrillator cannot store the selected energy so that selected and stored energy values differ, the LCD shows he message "Energy high" or "Energy low". The defibrillation pulse can be triggered all the same.

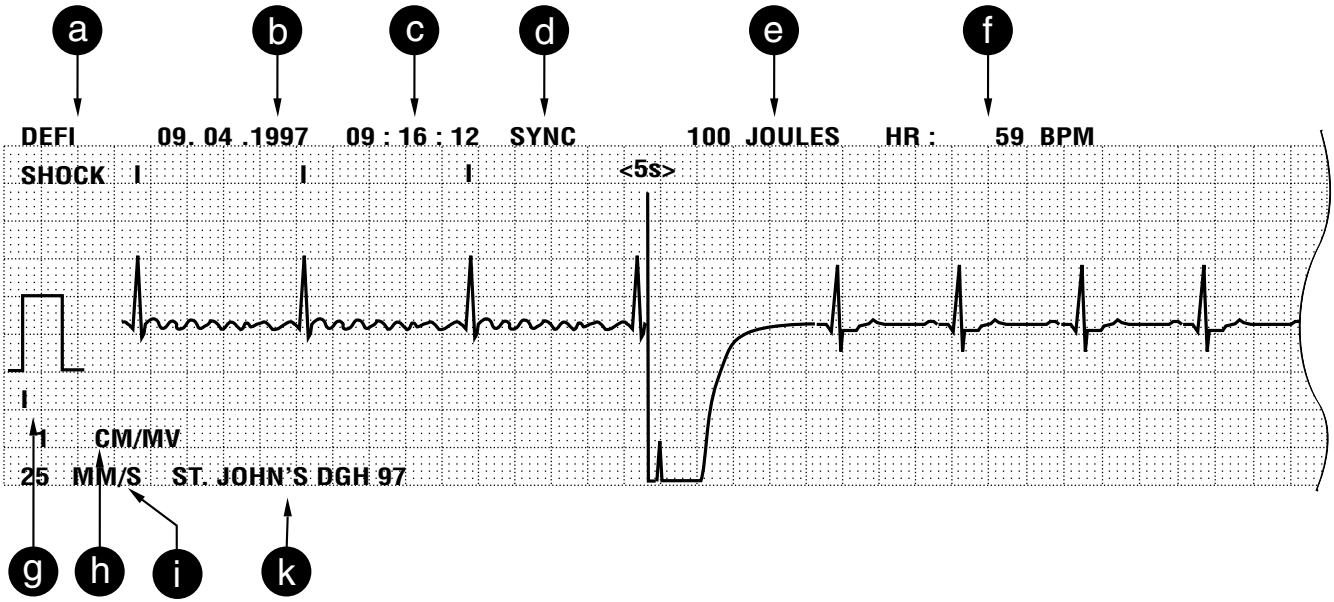

Figure 5-8. Example of a recording initiated by a defibrillation pulse

a initiation
b date
c time
d SYNC mode
e delivered energy
f heart rate
g ECG lead (here: EINTHOVEN I)
h sensitivity
i paper speed
k name of hospital/practice

Always switch off Cardio Serv before exchanging the defibrillation paddles.

* Once therapy has ended, set the selector switch to for monitoring of the patient's ECG.

* After use, switch off **CardioServ** (Set selector switch to).

* Clean electrodes and the defibrillator as described in section 13.

* After cleaning, return the paddles to their compartments.

* When using **CardioServ** with internal electrodes or pads, please refer to section 4.2 "Defibrillation with Internal Electrodes or Single-Use Pads".

5.3 Brief Operating Instructions (cardioversion)

ECG Acquisition with ECG Electrodes (this is the preferred method)

* Apply ECG electrodes and connect them to CardioServ, using the patient cable
* Turn on **CardioServ** (4) and set energy selector to required energy
* Select synchronized operating mode (Sync) and check LCD for regular trigger pulses; if they do not appear, select another lead (F1 ECG) — 1
* Remove paddles from their compartments and apply electrode cream
* Apply paddles to patient and initiate defibrillator charging — 2
* Wait for beep to sound and for available energy to be displayed
* Warn bystanders, do not touch the patient any more and trigger pulse; to do this, simultaneously press the buttons on both paddles; wait for shock to be delivered — 3
* Watch ECG, repeat defibrillation if necessary or set energy selector to , if defibrillation was successful
* Switch off **CardioServ** after use (energy selector at)
* Discard disposable electrodes, clean paddles and defibrillator

ECG Acquisition with Defib Pads

* Apply pads to patient and connect them to **CardioServ**; a patient cable must not be connected to the unit (**24**)!
* Turn on **CardioServ** (4) and set energy selector to required energy
* Select synchronized operating mode (Sync) and check LCD for regular trigger pulses; if they do not appear, acquire ECG with ECG electrodes — 1
* Initiate defibrillator charging Charge Shock — 2
* Wait for beep to sound and for available energy to be displayed
* Warn bystanders, do not touch the patient any more and trigger pulse; to do this, simultaneously press Charge Shock Shock on the device; wait for shock to be delivered — 3
* Watch ECG, repeat defibrillation if necessary or set energy selector to , if defibrillation was successful
* Switch off **CardioServ** after use (energy selector at)
* Discard disposable electrodes, clean paddles and defibrillator

6. Displaying and Monitoring the ECG

This section describes how to apply the ECG electrodes in order to display all 12 standard leads, and how to monitor the heart rate (adjusting alarm tone, QRS beep and alarm limits).

At the end of this section you will find a summary of all nesessary operating steps (brief operating instructions).

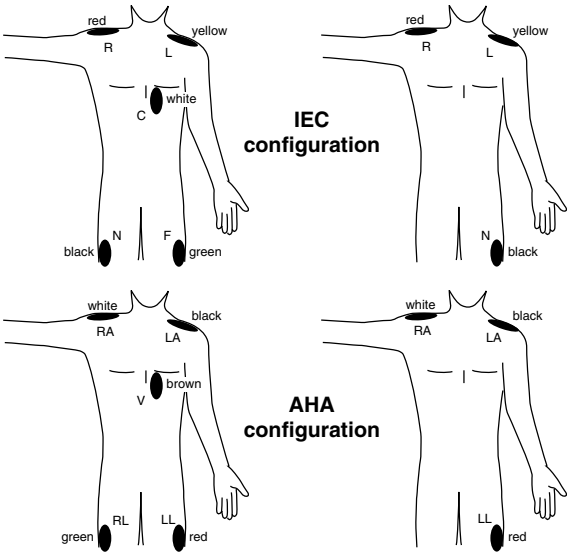

Figure 6-1. Electrode application points
5-lead cable (left)
3-lead cable (right)

☞ ***With a 3-lead cable only ECG leads I,II and III can be displayed.***

Caution ***When monitoring the patient via the adhesive defib pads, make sure that the energy selector is in the monitoring position .***

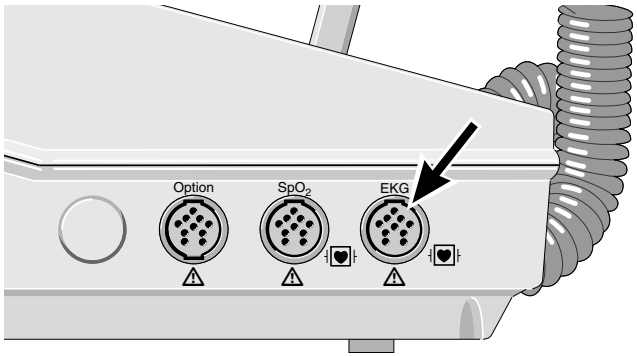

Figure 6-2. ECG signal input

6.1 Displaying the ECG

For a quick diagnosis the ECG signal can be sensed via the defibrillation paddles (see below). For more accurate examinations and heart-rate monitoring, however, ECG electrodes must be applied.

Either 3 or 5 electrodes can be used for ECG acquisition. In emergencies, 3 electrodes are sufficient. Use only silver/silver chloride electrodes. This type of electrodes prevents polarization voltages which may be caused by the defibrillation pulse, resulting in an ECG trace simulating cardiac arrest.

For detailed information on ECG signal acquisition, please refer to our application note on electrocardiography and to the relevant literature.

* Apply the electrodes as shown in Figure 6-1.

* Connect the patient cable to the electrodes and to the ECG signal input (Figure 6-2).

– If you prefer to use 5 ECG electrodes, apply 4 limb-lead electrodes, for instance, and one precordial electrode.

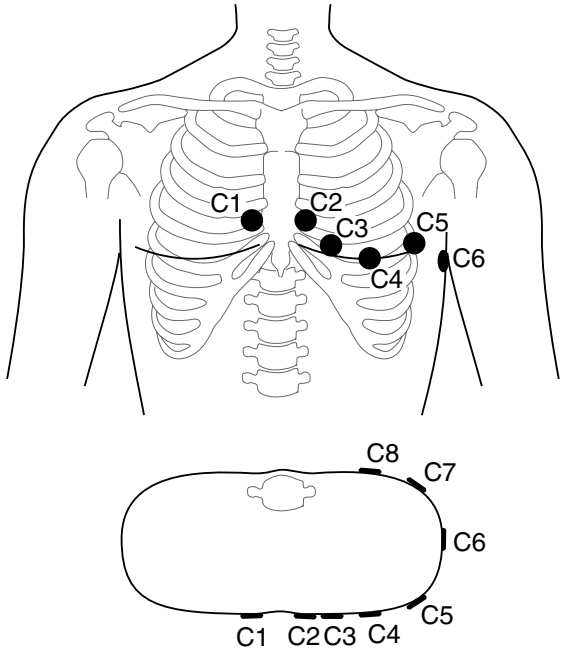

Figure 6-3. Chest electrode application points

C1 in the 4th intercostal space at the right sternal edge

C2 in the 4th intercostal space at the left sternal edge

C3 at the level of the 5th rib midway between C2 and C4

C4 in the 5th intercostal space on the left midclavicular line

C5 between C4 and C6 on the left anterior axillary line

C6 on the mid-axillary line at the level of C4

C7 in the 5th intercostal space on the left posterior axillary line

C8 in the 5th intercostal space on the left scapular line

☞ ***The C-electrodes of the IEC system shown here are the V-electrodes of the AHA system.***

– To obtain a recording of all 12 standard leads, attach the 4 limb-lead electrodes and apply suction electrode 217 144 01 to the thorax. This electrode is easy to move from one pick-up point to the next (C1 through C6, Figure 6-3). Use electrode lead 223 404 10 to connect the suction electrode to the patient cable. While recording the chest leads, leave softkey [I...III aV...V Paddle] set to V and simply move the chest electrode to application points C1 through C6 (C8).

– As an alternative, you can connect the 3-lead monitoring cable, Part No. 223 287 01 or Part No. 223 288 01 (with HF protection).

☞ ***In this case only leads I,II and III can be displayed.***

* Set the energy selector (4) to ⎍: This turns on **CardioServ.**

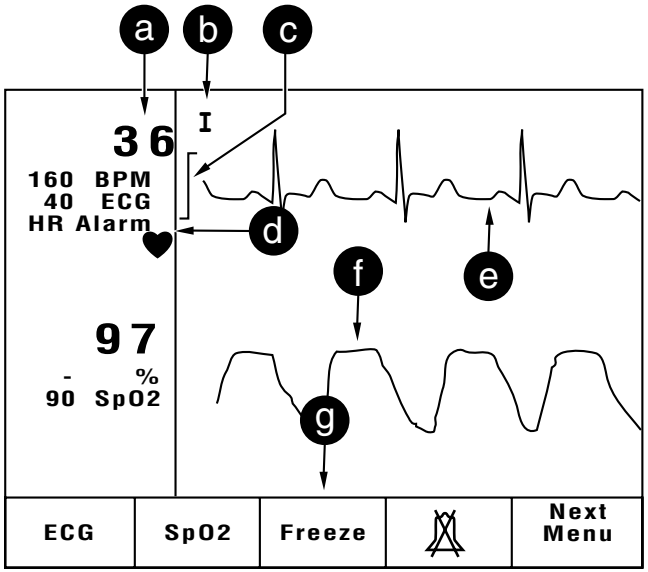

Figure 6-4. Main display

a heart/pulse-rate reading with alarm limits
b lead
c 1-mV calibration pulse
d alarm message, QRS blip
e channel 1: ECG
f channel 2: plethysmogram
g menu

> ***Filters will falsify the ECG signal. For diagnostic purposes, all filters should be disabled.***

The defibrillator beeps and displays a checkered pattern (LCD performance test). Next the software version is displayed, followed by the main display (Figure 6-4).

A field is reserved for technical alarms and messages above the heart and pulse rate reading.

The defibrillator selects the following default settings:

– EINTOVEN lead I (selectable)
– AC filter on/ muscle filter on (selectable)
– sensitivity of 1 cm/mV (selectable)

If you wish to select another lead or sensitivity, proceed as follows (these are only temporary changes which will not be saved):

* Press the **ECG** softkey to call up the ECG submenu.

* Use the **I...III aV...V Paddle** softkey to select a suitable ECG lead (shown at **b**, Figure 6-4).

* Use the **1 cm/mV** softkey to select the sensitivity.

Filters (AC line filter / muscle filter) enabled during signal acquisition render the ECG display insensitive to signal noise arising from the mains or from muscle tremor or motion. The filters, however, falsify the ECG signal, making it unsuitable for diagnostic purposes. The heart rate is always calculated from the unfiltered ECG. An artifactual ECG signal may thus lead to a wrong heart rate reading, even though the displayed, filtered ECG is “clean”.

☞ *The Freeze function may mask messages on the display.*

Freeze

* For a more detailed assessment of the ECG, you can freeze the trace with the Freeze softkey.

The current ECG continues to be displayed in the upper section of the LCD for monitoring, while the frozen segment appears in the bottom section. The monitoring function is still on.

When you press Freeze the erase bar moves to the right-hand screen edge, i.e., the entire display shows the period of time immediately prior to depression of Freeze.

The frozen ECG segment can be:

– printed out with the Freeze Print key (incl. a history of 4 seconds)

– stored with the Store Freeze key

– released with the Un-Freeze key.

Rotating the display (temporary)

The screen display can be rotated 180°.

* Press Next Menu to display the submenu.

* Press Display Flip to rotate the display.

Pressing the same key again restores the original orientation.

6.2 Monitoring the Heart Rate

☞ *CardioServ can be set up (Section 11 "Configuring the Defibrillator Settings") to automatically enable the audible alarm on power-up. The default alarm limits can also be preset.*

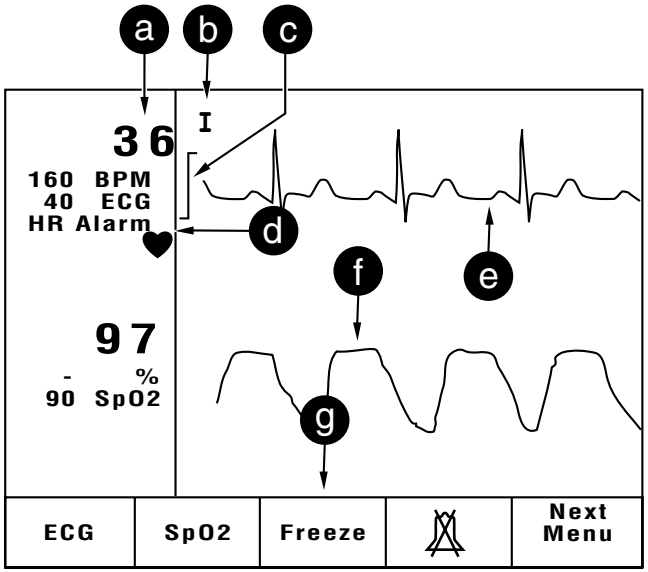

Figure 6-5. Main display

a heart/pulse-rate reading with alarm limits
b lead
c 1-mV calibration pulse
d alarm message, QRS blip
e channel 1: ECG
f channel 2: plethysmogram
g menu

With the factory settings unchanged, there will be no audible alarm upon power up (**F4** [🔔]). You enable the alarm tone by pressing **F4** once.

If the device sounds an alarm, you can press [🔔] to silence the **alarm tone**. Should the alarm cause persist, the alarm will recur after 120 s (the remaining time is displayed in the softkey). To permanently disable the audible alarm, press the key longer than 2 seconds. As a result the crossed-out bell symbol will appear.

The alarm limits can be modified either permanently via the defaults menu (section 11 "The Defaults Menu") or temporarily (see below).

If the heart rate violates one of the set limits for **more than 5 seconds CardioServ** gives alarm:

- the alarm tone sounds (selectable)
- the alarm cause is shown in the display (**d**, Figure 6-5)
- the violated limit value flashes
- the alarm recorder is started (selectable)
- the ECG is saved (4-s history, 6 seconds after alarm release). See section 7 "The Memories of CardioServ".

* Press [🔔] to silence the alarm.

If the alarm cause has been eliminated, the alarm is cleared; if it persists, the alarm recurs after 120 seconds.

> ***Warning***
>
> ***Do not rotate the screen display ("Display Flip" function) within 2 minutes of silencing the alarm tone. Otherwise the audio alarm would not be reactivated and the device would not emit an alarm tone for future alarms.***

When an electrode required for the selected ECG lead drops off, an alarm sounds and the "Check Electrode" message appears on the display.

Modifying Device Settings

Using keys **F1** to **F5** you can change the settings for ECG monitoring. In this case, however, the settings are only temporary and will not be saved. Permanent adjustments are only possible via the defaults menu (section 11 "Configuring the Defibrillator Settings").

Adjusting Alarm Limits

* Press the ECG softkey to display the ECG menu (Figure 6-6).
* Press Alarm Limits to change the alarm limits. The alarm menu will be displayed (Figure 6-7).
* The **+** keys increase the values, the **-** keys decrease them in steps of 5 BPM. If you hold the key depressed, the digits change at a higher rate.

I...III aV...V Paddle	1 cm/mV	Alarm Limits	Alarm Printout	back

Figure 6-6. Next menu

High Alarm - + ECG	Low Alarm - + ECG	back

Figure 6-7. Alarm menu

> ☞ ***You can disable the alarm limits by selecting a value outside the adjustment range.***

☞ *CardioServ automatically returns to the main menu when no function keys are pressed for more than 30 s.*

HR Source ECG	QRSPulse Beep OFF	Memory	Display Flip	back

Figure 6-8. The submenu

☞ *With the C-LOCK ECG synchronization function enabled, the QRS beep is triggered by the ECG signal even when the selected heart rate source is the pulse signal.*

Selecting the HR Source

CardioServ devices with SpO_2 measuring system allow the selection of the heart/pulse-rate source (heart rate from ECG or pulse rate from the SpO_2 signal). The source is indicated by "ECG" or "Pulse" below the parameter reading.

* Display the submenu with the [Next Menu] key.

Figure 6-8 will appear.

* Select "ECG" or "SpO_2" with the [HR Source ECG] key.

Enabling/Disabling the QRS Beep

* Display the submenu (Figure 6-8) with the [Next Menu] key.

* Enable or disable the QRS or pulse beep with the [QRSPulse Beep OFF] key, as required.

6.3 Monitoring Pacemaker Patients

If several adverse conditions exist at once, the possibility that pacing pulses are interpreted as QRS complexes should be considered. For safety, always watch pacemaker patients closely.

The device does not recognize pacing pulses with an amplitude below 20 mV.

When monitoring pacemaker patients, it is important that the device counts only the QRS complexes and not the pacing pulses from the pacemaker. For this reason, **CardioServ** comes with an electronic circuit that filters out pacemaker pulses. However, in exceptional cases, depending on the pacemaker model involved and the electrode placement, the compensation algorithm following every pacing pulse may simulate a QRS complex. Every pacemaker must provide an oppositely charged current (reverse current) after delivering a pacing pulse. Ineffective stimulation (absence of QRS complexes) can lead to misinterpretation, so that alarm is not released in cases of bradycardia (slow heart rate) or cardiac arrest.

For this reason we recommend the plethysmogram (SpO_2) for monitoring of pacemaker patients. Also, set the HR source to “Pulse”.

You should disable the C-LOCK synchronization to prevent that frustraneous pacing pulses are counted as QRS complexes.

Whether or not the device interprets the pacemaker compensation algorithm as a QRS complex depends on the pacemaker pulse parameters (See section 14 “Technical Specifications”).

For pacemaker patients, the ECG amplitude should be greater than 1 mV.

6.4 Brief Operating Instructions

Displaying the ECG

* Apply ECG electrodes and connect them to **CardioServ**.
* Set energy selector to .
* Display the ECG menu (key **F1** ECG) and select ECG lead (**F1**).
* Adjust amplitude (**F2**).
* Freeze and release the ECG, if desired, with **F3** (main menu).

Monitoring the Heart Rate

* Display the ECG as described above.
* Enable alarm tone with **F4**.
* Silence alarm with **F4**, if alarm cause persists, the alarm recurs after 120 seconds (or disable the audible alarm permanently by pressing **F4** longer than 2 s).

Modifying the Heart-Rate Alarm Limits

* Press **F1** ECG to display the ECG menu.
* Press **F3** to display the alarm limits menu.
* Decrease the values with **F1** and **F3**, increase them with **F2** and **F4**.

7. The Memories of CardioServ

This section of the manual informs you

– **about the memories of CardioServ**

– **how to print out the stored information**

– **how to clear the memories**

CardioServ comes with 3 different memories:

– a text memory
– an event memory
– a trend memory

All information concerning device operation goes into the **text memory** where it is saved with the time of day (e.g., device on, device off, alarms, shocks, etc.). **CardioServ** can save up to 80 such events. When the memory is full, the device updates the information automatically by saving new events and deleting old ones. Moreover, all three memories can be cleared in one action (see below).

To print out the stored information, proceed as follows:

* Press [Next Menu] to display the submenu (Figure 7-1).

* Press [Memory] to display the memory menu (Figure 7-2).

* Press [Print Text] to print out the information stored in the text memory (Figure 7-3).

HR Source ECG	QRSPulse Beep OFF	Memory	Display Flip	back

Figure 7-1. Submenu

Print Text	Print Event	Print Trend	Memory Clear	back

Figure 7.2. Memory menu

```
DEVICE OFF . . . . . : 17:15:02  28.06.1997
DEVICE ON  . . . . . : 17:15:08  28.06.1997
HR ALARM 335BPM:  17:15:09  28.06.1997
SHOCK 349JOULES:  17:15:25  28.06.1997
HR ALARM  61BPM:  17:16:20  28.06.1997
HR ALARM  60BPM:  17:17:44  28.06.1997
HR ALARM  61BPM:  17:19:31  28.06.1997
SHOCK 205JOULES:  17:20:12  28.06.1997
DEVICE OFF . . . . . : 17:38:17  28.06.1997
DEVICE ON  . . . . . : 17:52:09  28.06.1997
```

Figure 7-3. Printout from text memory

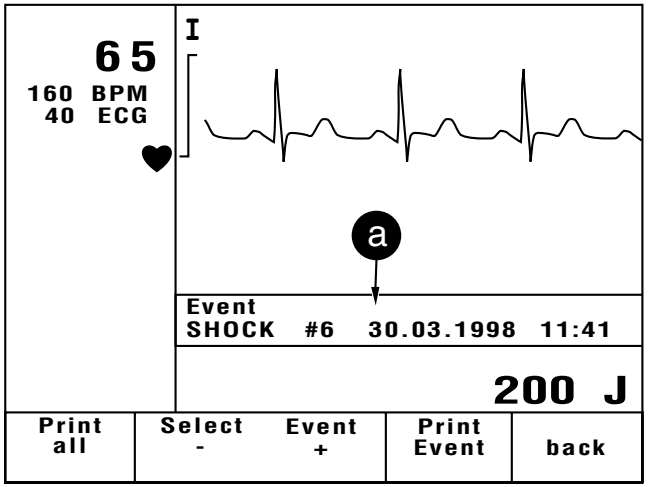

Figure 7-4. "Print Event" menu

The **event memory** contains up to 40 ECG strips of 16 seconds duration, each with a history of 4 seconds. The event strips are recorded either automatically (upon violation of a heart-rate limit, delivery of the shock and modification of the pacemaker settings, provided the pacemaker is turned on) or manually with the [Store Freeze] key. When the memory is full, the device updates the information automatically by saving new events and deleting old ones. Moreover, all three memories can be cleared in one action (see below). Recordings initiated by a defibrillation shock are blanked for 5 seconds after the 4-second strip before the shock. After the blank, the recording continues for another 10 seconds.

To print out the stored events, proceed as follows:

* Press [Next Menu] to display the submenu (Figure 7-1).
* Press [Memory] to display the memory menu (Figure 7-2).
* Press [Print Event] to display the print-event menu (Figure 7-4).

Now you can

* select an event with the + and - keys (The event is displayed at **a** in Figure 7-4) and initiate the printout with [Print Event] or
* print all stored events with [Print all] (starting with the event displayed at **a**, Figure 7-4) or
* press [back] to return to the memory menu.

HR Source ECG	QRSPulse Beep OFF	Memory	Display Flip	back

Figure 7-1. Submenu (repeated)

Print Text	Print Event	Print Trend	Memory Clear	back

Figure 7-2. Memory menu (repeated)

45 min HR Print	9 h HR Print	45 min SpO2 Print	9 h SpO2 Print	back

Figure 7-5. "Print trend" menu

The **CardioServ trend memory** contains the HR and SpO_2 readings of the past 45 minutes and 9 hours. This memory, too, is updated automatically. The stored trends can be printed out as follows:

* Press [Next Menu] to display the submenu (Figure 7-1).
* Press [Memory] to display the memory menu (Figure 7-2).
* Press [Print Trend] to display the print-trend menu (Figure 7-5).

Now you can

* print the 45-min HR trend with [45 min HR Print]
* print the 9-hour HR trend with [9 h HR Print]
* print the 45-min SpO_2 trend with [45 min SpO2 Print]
* print the 9-hour SpO_2 trend with [9 h SpO2 Print]
* press [back] to return to the memory menu.

Clearing the Memories

* Press [Next Menu] to display the submenu (Figure 7-1).
* Press [Memory] to display the memory menu (Figure 7-2).
* Press [Memory Clear] for 2 seconds to clear all three memories in one action.

8. Recording

This section describes

- **how to initiate a manual recording**
- **in which situations the recorder operates automatically**
- **how to load chart paper**

8.1 Manual Recordings

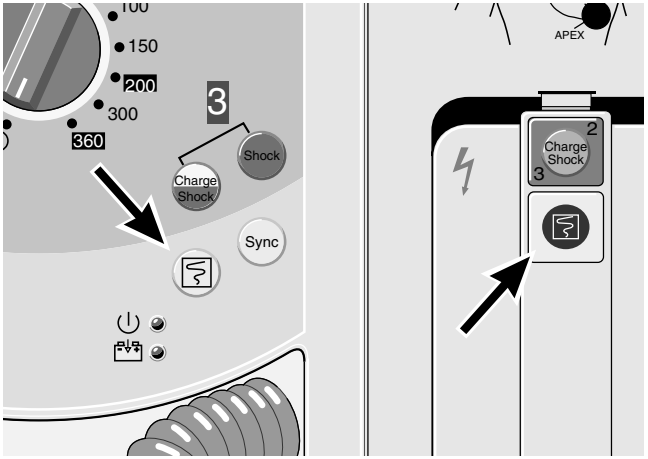

Figure 8-1. Keys to initiate a recording

The keys are used to start and stop manual recordings. When "Cont. Printout" in the defaults menu is "off" (Default), **CardioServ** will record the ECG shown on the display for 16 seconds. The recorder can be stopped before that with . When "Cont. Printout" is "on", **CardioServ** will record the ECG until stopped with . The paper speed is 25 mm/s. A calibration pulse is recorded first (Figure 8-2). The following information is annotated in the margin of the recording strip:

- **a** text indicating that this is a manual recording
- **b** date
- **c** time
- **d** active filters
- **e** delivered energy
- **f** heart rate
- **g** ECG lead
- **h** sensitivity
- **i** paper speed
- **k** hospital/department name

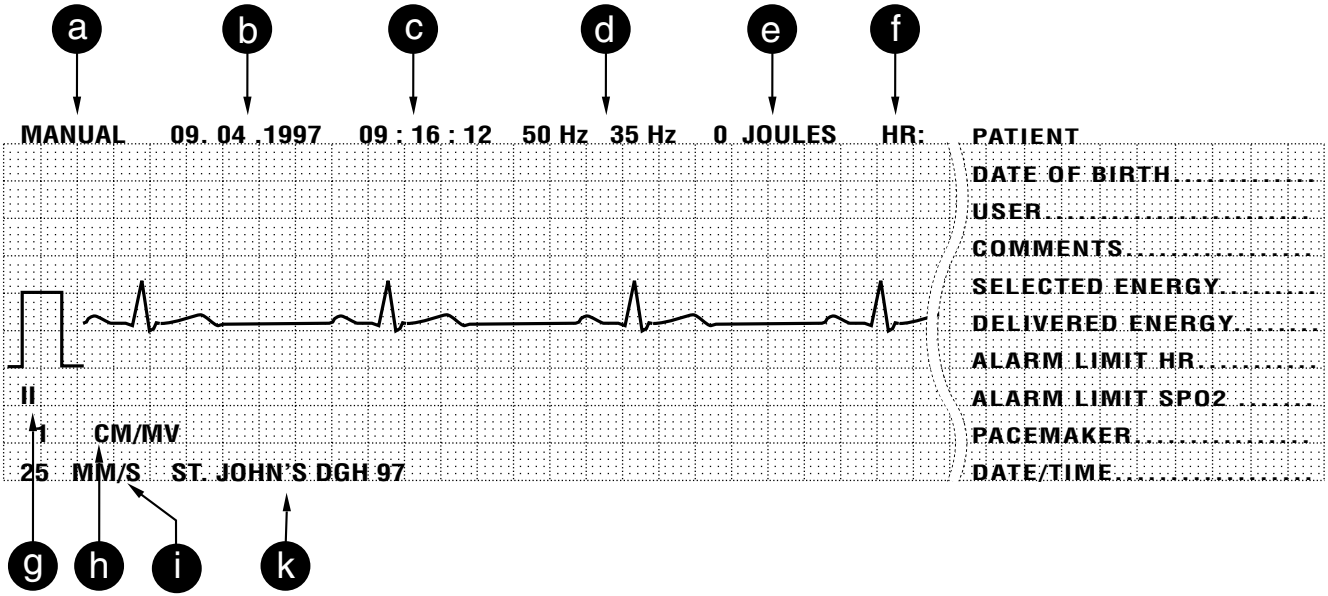

Figure 8-2. Manual recording

8.2 Automatic Recordings

It is important that the chart paper exit is unobstructed. If this is not ensured, the paper may be pulled back into the device and wrap around the transport roller. When this happens, remove the paper jam as follows:

- *open the paper compartment*
- *carefully pull out the tangled paper and tear it off the strip*
- *re-load the chart paper (section 8.3).*

☞ *You can obtain a copy of the displayed image by simultaneously pressing the two contrast adjustment keys.*

A recording is initiated automatically with each delivered defibrillation shock. Via the defaults menu (section 11) you can select automatic recordings to be triggered by each violation of an alarm limit. An automatic recording covers a period of 16 seconds, including a history of 4 seconds. The following information is annotated in the margin of the recording strip (Figure 8-2):

a Message indicating the reason for the recording
b Date
c Time
d Active filters
e Delivered energy
f Heart rate
g ECG lead
h Sensitivity
i Paper speed
k Hospital/department name

8.3 Loading Chart Paper

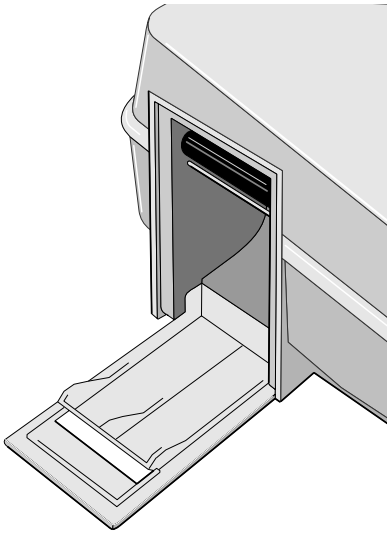

Figure 8-3. Opening the paper compartment

To prevent damage to the printhead use the original GEMS IT CONTRAST® chart paper only (Part No. 226 130 02).

* Push the cover of the paper compartment upward and fold it out (Figure 8-3).

* Remove the empty sleeve of the old paper roll by pulling on the white plastic tab.

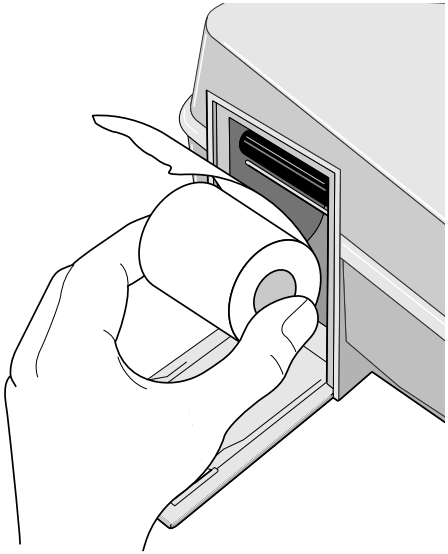

Figure 8-4. Inserting the paper roll

* Insert the new roll as shown in Figure 8-4.

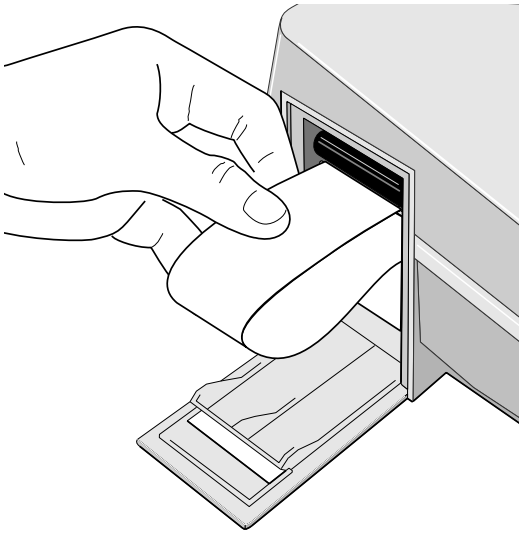

Figure 8-5. Inserting the leading edge

* Feed the leading edge of the paper under the paper transport roller (Figure 8-5) and keep pushing it forward until it appears above the roller.

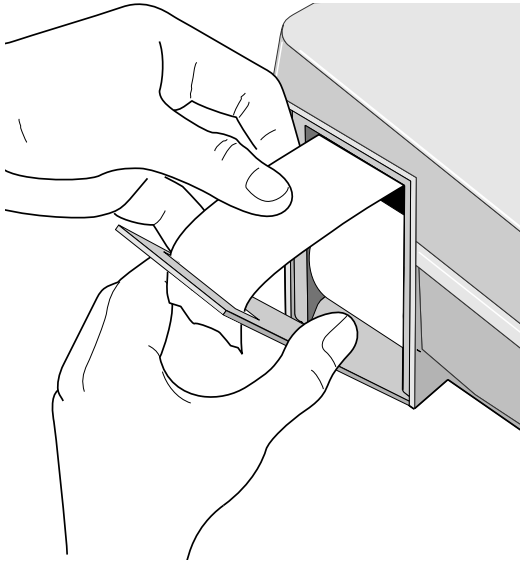

Figure 8-6. Feeding the leading edge through the aperture

* Feed the leading edge of the paper through the exit in the cover as shown in Figure 8-6.

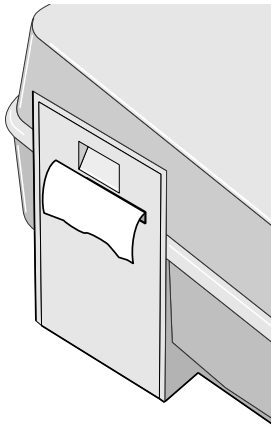

Figure 8-7. Closing the cover

* Close the cover. While doing so, pull firmly on the paper strip to ensure that it does not get caught behind the cover (Figure 8-7).

The last 3 meters of the roll are marked with a red stripe. Insert a new roll in time to ensure that all alarm recordings are documented.

☞ ***Thermorecordings should only be stored in transparent envelopes made of polyethylene, since PVC bleaches the text and traces (if in doubt, insert a sheet of tissue paper in between).***

9. Oxygen Saturation SpO_2

This section of the manual explains

– **the oxygen saturation measuring method**

– **how to apply the sensors**

– **points to note during SpO_2 measurement**

9.1 General Information

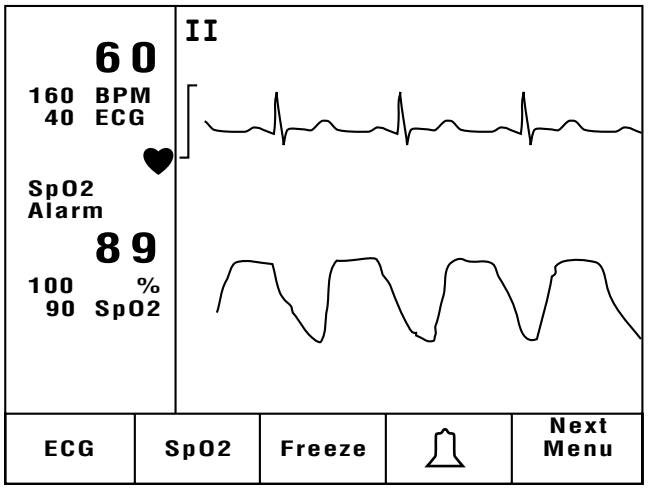

Figure 9-1. Display of the SpO_2 reading and the plethysmogram

> ***Caution** Pulse oximetry is not suitable for oxygen monitoring in fetuses before or during birth. Moreover, it is not suitable for use on patients with carbonmonoxide poisoning.*

> ***Caution** Elevated levels of CO-Hb and Met-Hb can influence the SpO_2 readings. Also dyes in the blood (e.g. Cardiogreen) can impair the measuring accuracy of the system.*

SpO_2 measurement is employed to determine the oxygen saturation of hemoglobin in the arterial blood. Alarm limits can be adjusted to monitor levels of oxygen saturation. A plethysmographic waveform is displayed in channel 2 (Figure 9-1).

Arterial oxygen saturation is measured by a method called pulse oximetry. It is a continuous, non-invasive method based on the different absorption spectra of reduced hemoglobin and oxyhemoglobin.

Therefore the sensors consist of a light source (two LEDs in most cases) and a photodetector on the opposite side which collects the incident light. The light (red and infrared range between 660 nm and 940 nm) from the LEDs is transmitted through the blood and tissue components of the finger, ear lobe or foot. The photodiode in the sensor measures the light that passes through and converts it into an electrical signal. The pulsatile component of the signal is used to build the plethysmogram.

Literature

WUKITSCH, M.W.; PETTERSON, M.T.; TOBLER, D.R.;POLOGE, J.A.: Pulse Oximetry: Analysis of Theory, Technology, and Practice, J. Clin. Monit. 4: 290–301 (1988)

CECIL, W.T.; THORPE, K.J.; FIBUCH E.E.; TUOHY, G.F.: A Clinical Evaluation of the Accuracy of the Nellcor N-100 and Ohmeda 3700 Pulse Oximeters, J. Clin. Monit. 4: 31–36 (1988)

C-LOCK ECG Synchronization

The C-LOCK ECG synchronization feature enables the monitor to use an ECG signal as a reference point for identifying the pulse and synchronizing saturation measurements. This enhances the performance of the monitor in the presence of patient movement and when the patient's perfusion is poor.

When an ECG signal is present during SpO_2 measurement, the monitor is receiving two separate signals that reflect cardiac activity: an optical signal from the sensor and an electrical signal from the ECG. The time that elapses between the ECG R-wave and the optical pulse detected at the sensor site depends on the patient's physiology, the heart rate and the location of the sensor. However, for a given patient the length of the delay is relatively stable. Through C-LOCK ECG synchronization, the monitor uses that time relationship to identify good pulses and reject nonsynchronized artifacts.

Application Hints

- Use only the sensors listed in section 15 "Order Information and Accessories". Apply the sensors as described in their instructions for use. Carefully observe all information and cautions given in these instructions.
- Take care that the sensor does not exert too much pressure on the tissue, as this would result in wrong readings and blistering. The blisters are not caused by overheating but by lack of ventilation.
- Exercise extreme care to assure continued circulation distal to the sensor site after application.
- Change the application site at least every 24 hours to allow the skin to breathe.
- Excessive ambient light impairs signal quality. This can be prevented by covering the sensor site with a cloth.
- Simultaneously determining the cardiac output by means of dye dilution may prevent SpO_2 measurement.
- When circulation of blood is impaired (blood-pressure cuff or extreme vascular resistance), it may not be possible to determine SpO_2 values or the pulse rate.
- Remove nail polish and artificial fingernails before applying the sensor, as these may affect the reading.
- Do not apply the finger sensor to the same arm as a blood-pressure cuff.

In order to minimize motion artifact:

– take care to provide an ECG of good quality (C-LOCK ECG synchronization)

– use a new sensor with fresh adhesive backing

– move the sensor to a less active site

– select a slow integration time.

When monitoring SpO_2 during electrosurgical intervention, take care that:

– **CardioServ** is powered from the built-in battery or from a different power circuit than the electrosurgical unit

– the ground pad is close to the surgical site

– the sensor is applied as far from the surgical site, the ground pad and the electrosurgical unit as possible.

In the presence of AC line interference

– When interference signals from the power line are present, square waves may be displayed instead of the plethysmogram. In this situation we recommend to disconnect the device from the power line and operate it on battery power.

☞ *The ECG signal (section 6.1 "Displaying the ECG") is a prerequisite for the proper functioning of the C-LOCK ECG synchronization feature.*

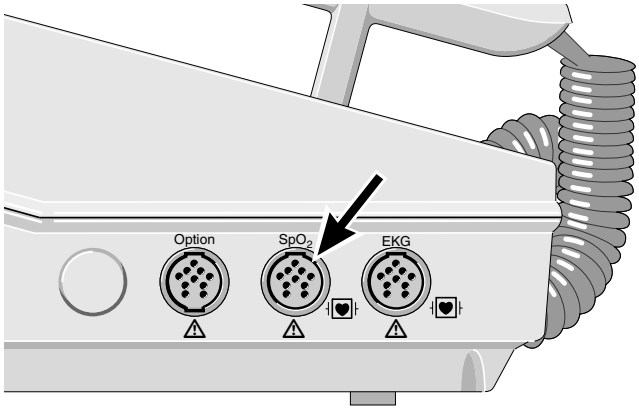

Figure 9-2. SpO_2 sensor connection

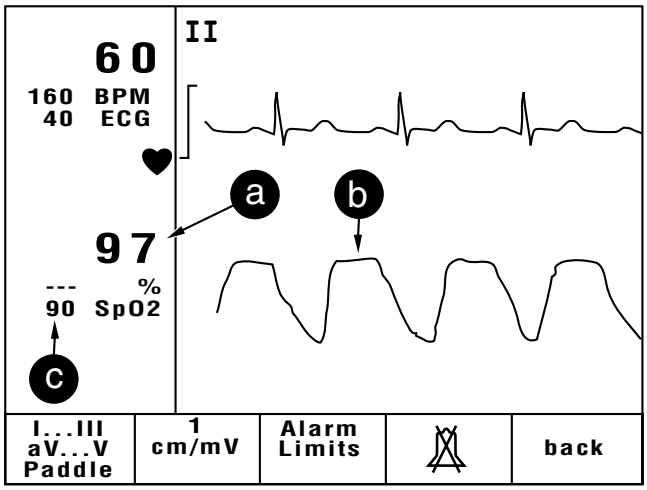

Figure 9-3. SpO_2 value and plethysmogram

a SpO_2 value

b plethysmogram

c SpO_2 alarm limits (upper limit disabled)

9.2 Measuring and Monitoring Oxygen Saturation

* Turn on **CardioServ** (switch position ⎍).

* Apply the sensor as described in the instructions for use enclosed with the sensor.

* Connect the sensor to **CardioServ** (**SpO_2** connection, Figure 9-2).

Within a few seconds the SpO_2 reading and the plethysmogram will be displayed (Figure 9-3).

Please note: The following adjustments are temporary and, contrary to the settings of the default menu (Section 11 "Configuring the Defibrillator Settings"), will not be saved.

☞ *Disable the C-LOCK ECG synchronization function for monitoring of pacemaker patients (section 6.3)*

Figure 9-4. SpO_2 menu

Enabling/Disabling the C-LOCK ECG Synchronization

With the factory settings unchanged, the C-LOCK ECG synchronization feature is inactive when the **CardioServ** is switched on. If an ECG signal is available, enable the synchronization feature as follows:

* Press the SpO2 softkey to display the SpO_2 menu (Figure 9-4) (only available when SpO_2 sensor is connected to the unit).

* Press the C-Lock OFF softkey to enable (ON) the C-LOCK feature (or disable the feature by pressing the key again).

Selecting the Integration Time

The integration time is the time over which the SpO_2 readings are averaged. Selectable times are 4, 8 (default) and 12 seconds. The integration time of 12 seconds should only be selected in exceptional cases.

* Press the SpO2 softkey to display the SpO_2 menu (Figure 9-4).

* Press Integ. Time 12 s to select an integration time.

Caution

If, in monitoring the patient, several adverse conditions exist at once, a disturbed signal may go unnoticed. Artifacts could then be capable of simulating a plausible reading, and no alarm would be released. To assure reliable monitoring, the sensor application and signal quality should be verified from time to time.

Caution

When monitoring the pulse rate derived from the SpO_2 signal instead of the heart rate, select an integration time of 4 s or 8 s. Do not select 12 s.

C-Lock ON	Integ. Time 12 s	Alarm Limits		back

Figure 9-4. SpO_2 menu (repeated)

High Alarm - SpO2 +	Low Alarm - SpO2 +	back

Figure 9-5. Alarm limits menu

☞ *SpO_2 alarms are similar to HR alarms. Please refer to section 6.2 "Monitoring the ECG".*

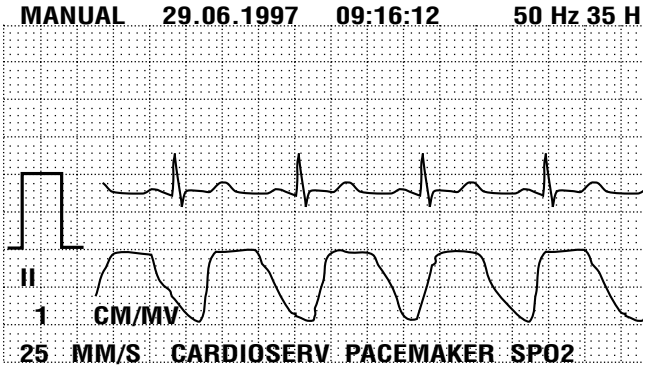

Figure 9-6. ECG and plethysmogram

Adjusting SpO_2 Limits

* Press [SpO2] to display the SpO_2 menu (Figure 9-4).
* Press [Alarm Limits] to display the alarm limits menu (Figure 9-5).
* The **+** key increases the limit value, the **-** key decreases it.

SpO_2 alarms neither initiate an alarm recording nor are they saved to the event memory.

Printing the Plethysmogram

The recordings, no matter whether they are initiated manually or automatically, always display the plethysmorgram in channel 2.

For your notes

10. Pacing

This section of the manual explains

- **the pacemaker uses**
- **the points to note during pacing**
- **pacemaker operation**

10.1 General Information

Application and Functional Description

The transcutaneous pacemaker of **CardioServ** is applied in emergencies for external (transcutaneous) cardiac stimulation. It is also used as a temporary aid in cases of acute arrhythmias or Stokes-Adams attacks. Some forms of bradycardia and tachycardia can be treated as well.

The pacemaker offers two modes of operation: demand and fixed-rate pacing.

The pacing pulses are delivered through the defibrillation pads.

Rules for Application of External Pacemakers

These rules are valid for all pacemakers, regardless of model and manufacturer.

All electrical devices that deliver energy to patients in any form or that have an electrically conductive connection to the patient present a possible hazard.

The safe application of the device lies in the hands of the user; thus, it is very important to observe the following rules:

* Pacemakers may only be used under the supervision of qualified medical staff.

* The safe application necessitates expert knowledge, good organization, special care in selecting the technical equipment and regular maintenance.

* Medical-technical devices such as the **CardioServ** must only be applied by persons who are adequately trained in the use of such equipment.

* Before application, the user must check the unit for functional safety.

* The patient's ECG must be monitored to allow the user to determine capture. Furthermore, at least one of the persons present must be familiar with the application of the defibrillator.

Caution

Due to their functional requirements pacemakers operate with high voltages and are thus equipped with special non-accessible outputs. Nevertheless, it is important not to come into contact with the voltage-conducting contacts via conductive metal objects, such as tweezers, as long as the pacemaker is operating. Currents passing through the heart which exceed 10 µA may induce ventricular fibrillation.

Caution

Switch the pacemaker on and off as follows:

Switching the pacemaker on:

1. *Apply the pace pads*
2. *Connect pads to CardioServ via the adapter lead*
3. *Switch on CardioServ*
4. *Switch on the pacemaker*

Switching the pacemaker off:

1. *Switch off the pacemaker*
2. *Switch off CardioServ*
3. *Disconnect adapter lead from CardioServ*
4. *Remove pace pads*

Caution

Determine capture by measuring the pulse rate, not the heart rate.

Each of the following rules must be observed:

* Check the performance of the defibrillator at hand.

* When positioning the patient ensure that no electrically conductive connections are created between the patient and earthed metal parts (also beware of puddles, etc.). Although the pacemaker pulse current output is required to be electrically isolated (floating), this is an additional safety precaution to ensure that the pacemaker current pulse only flows between the pacemaker electrodes.

* Apply electrodes, arrange electrode leads and connect them to **CardioServ**. Use only the electrodes and leads listed in section 15 “Order Information and Accessories”.

* Operate the pacemaker as described in this manual.

10.2 Application of Single-Use Defibrillation Pads

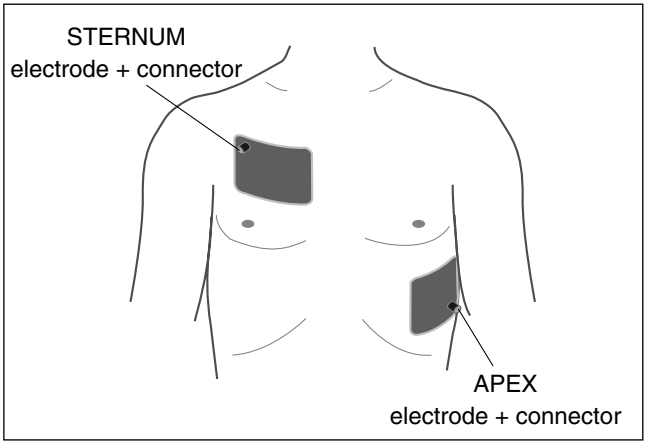

Figure 10-1. Defibrillation pad placement

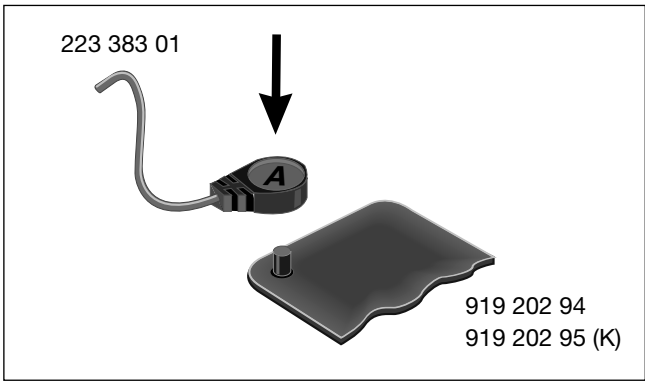

Figure 10-2. Connecting the pad to the cable

The single-use defibrillation pads (part no. 919 202 94 adult pads, part no. 919 202 95 pediatric pads) can be used for

– defibrillation/cardioversion (refer to section 4.2 “Defibrillation with Internal Electrodes or Defibrillation Pads”)

– ECG monitoring

– transcutaneous pacing.

Below we will explain the correct pad application for transcutaneous pacing

* Use pads before their expiration date.

* Apply the pads as follows:

– Shave each site. This improves conductivity and makes removal of the pad easier.

– Place the pads on the patient so that the connectors point to either side of the patient and that the cables are not hindering patient treatment.

– The electrodes are pregelled; therefore do not use additional contact cream or paste.

– Do not use pads, if the gel has dried out.

– Peel off the backing from each pad and place the pad carefully on the appropriate site.

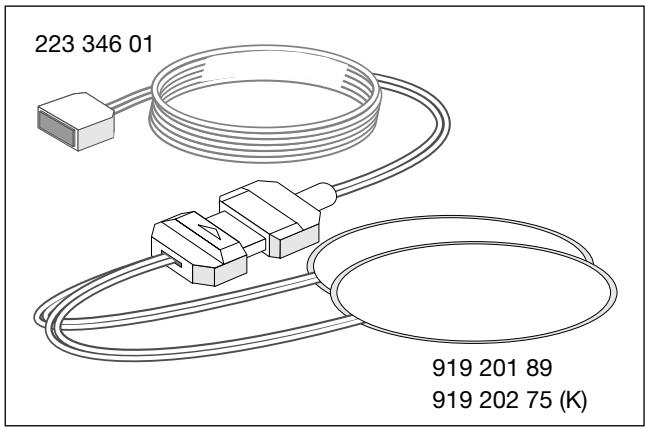

Figure 10-3. Connecting the defib pads to the adapter cable

Caution

Should a patient require defibrillation during transcutaneous pacing, immediately select the required energy with the energy selector, and push the Charge/Shock button. The pacemaker automatically selects a current of 0 mA in this situation. The shock is delivered by pressing the Shock buttons (as described in section 4.2).
Should the patient require further pacing, resume pacing by following the instructions in sections 10.3 (Demand Mode) or 10.4 (Fixed-Rate Mode).

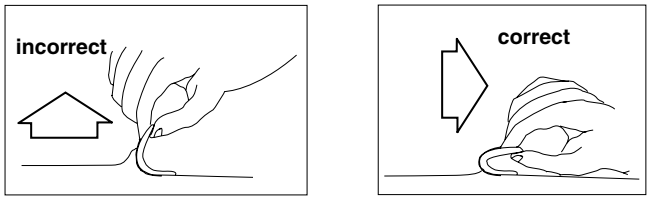

Figure 10.4. Removing defibrillation pads

* Then press the connector of cable 223 383 01 on to the electrode contact pin until you hear it click into place. Observe the connector labels: “A” =apex, “S” = sternum.

The round adhesive electrodes (part. no. 919 201 89) can be used with adapter lead 223 346 01. When connecting the electrode to the lead, take care that they engage properly. To disconnect them, simply press on the rear part of the catch (Figure 10-3).

* After use, carefully peel off the pads from the patient’s skin (Figure 10-4) and discard them immediately.

Warning

Discard disposable defibrillation pads immediately after use. Do not reuse them!

☞ ***If the ECG signal is extremely noisy and the AC line filter is not sufficient to provide a clean signal, the demand mode operation of the CardioServ may be disturbed. In this situation the message “Check pace pads” will be displayed. To reduce the interference signal, reapply the pads, carefully observing the application instructions.***

10.3 Demand Mode

Observance of the pacemaker application rules stated in section 10.1 is an absolute must to ensure the safe and successful use of the pacemaker.

Caution: The pacing pulses are delivered via the defibrillation pads. These must be applied to the patient as explained in section 10.2.

The pacemaker can be switched on only when the pace pads are connected (otherwise a message will be displayed to inform the user of missing electrodes).

In the demand mode the pacemaker does not deliver a pacing pulse as long as the patient's intrinsic heart rate exceeds the set pacer rate. When the heart rate drops below the pacer rate, the pacemaker starts delivering pacing pulses. For this reasons the ECG must be continuously monitored. The necessary synchronization pulses are automatically transmitted to the pacemaker.

During pacing, always set the energy selector to the position. This prevents that a defibrillation pulse is triggered inadvertently.

Demand mode is the method of choice when bradycardia or asystole is expected to develop after critical events. Controlling the pacemaker in this manner precludes the possible competition between intrinsic excitation and external pacing pulses which could result in ventricular fibrillation.

* Acquire the ECG signal as described in section 6.1 "Displaying the ECG".

* Verify that the pads are properly applied and connected to **CardioServ.**

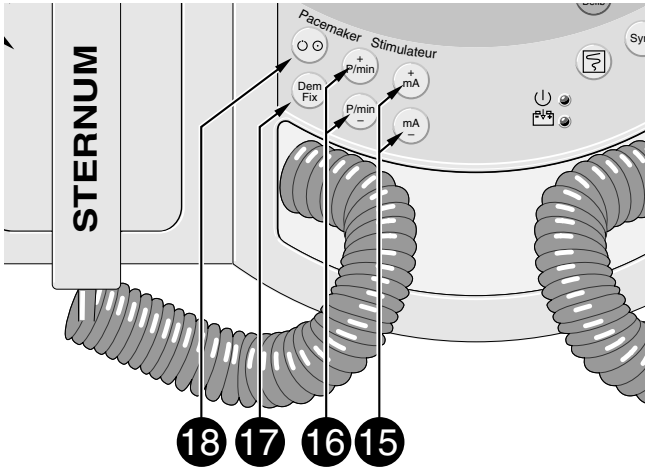

Figure 10-5. Pacemaker operating controls

15 Buttons for selection of the pacer output

16 Buttons for selection of the pacer rate

17 Pacing mode selection button (Fix/Demand)

18 toggles the pacemaker on and off (press button longer than 2 seconds to turn the pacemaker off)

☞ ***The default pacer rate can be preset (Defaults menu).***

* Press the button to switch on the pacemaker (Figure 10-5). The pacemaker defaults to the demand mode and to a pacer rate of 60 BPM (selectable).

* Using the mA button, select a low pacer output (e.g. 20 mA)

* Increase the pacer rate with the P/min button until the asterisk (**a**, Figure 10-6) just begins to flash: The pacer rate is now identical with or just above the intrinsic heart rate.

* Press the mA button to slowly increase the pacer output to a level which ensures consistent responses from the heart.

* Now select the required pacer rate with buttons P/min and P/min.

* Increase the pacer output by another 5 mA to achieve reliable stimulation.

* To verify the success of the treatment, watch the ECG on the screen. You can press the Sync button to view the trigger marks on the display.

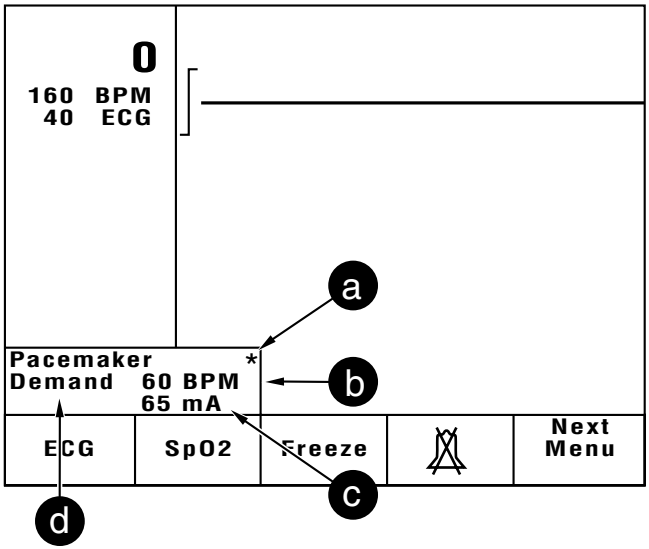

Figure 10-6. Screen display with pacemaker switched on

a asterisk, flashing with every delivered pacing pulse

b pacing rate

c pacing current

d pacing mode

☞ ***If the defibrillator is put into operation during pacing, the pacemaker automatically selects an output of 0 mA***

* At the end of the intervention, **first turn off the pacemaker, then remove the pads carefully.**

In order to turn off the pacemaker, button ⊙⊙ must be held down for at least 2 seconds. This safety precaution has been taken to prevent the pacemaker being turned off inadvertently. For this reason it is not possible to switch off **CardioServ** while the pacemaker is still on.

10.4 Fixed-Rate Mode

> ***Observance of the pacemaker application rules stated in section 10.1 is an absolute must to ensure the safe and successful use of the pacemaker.***

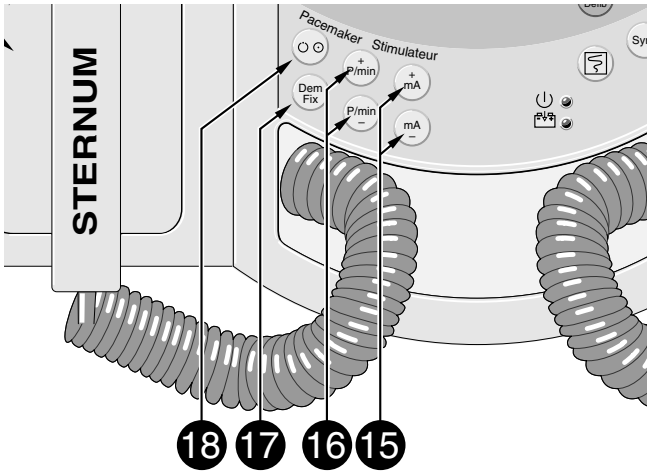

Figure 10-7. Pacemaker operating controls

15 Buttons for selection of the pacer output
16 Buttons for selection of the pacer rate
17 Pacing mode selection button (Fix/Demand)
18 toggles the pacemaker on and off (press button longer than 2 seconds to turn the pacemaker off)

> ***During pacing, always set the energy selector to the ⎍, position. This prevents that a defibrillation pulse is triggered inadvertently.***

Caution: The pacing pulses are delivered via the defibrillation pads. These must be applied to the patient as explained in section 10.2.

The pacemaker can be turned on only when the pace pads are connected (otherwise a message will be displayed to warn the user of missing electrodes).

In the fixed-rate mode the pacemaker delivers pacing pulses at a selectable rate and output setting. The selected rate is “fixed”, i.e., it does not take into account intrinsic action of the heart. This mode of operation should be selected in cases of asystole. Some forms of bradycardia and tachycardia can be corrected with fixed-rate pacing, but transcutaneous emergency pacing is not the therapy of choice in these instances.

* Verify that the electrodes are properly applied and connected to **CardioServ.**

* Press the ⏻ button, to switch on the pacemaker (Figure 10-7). The pacemaker defaults to the demand mode and to a pacing rate of 60 BPM (selectable).

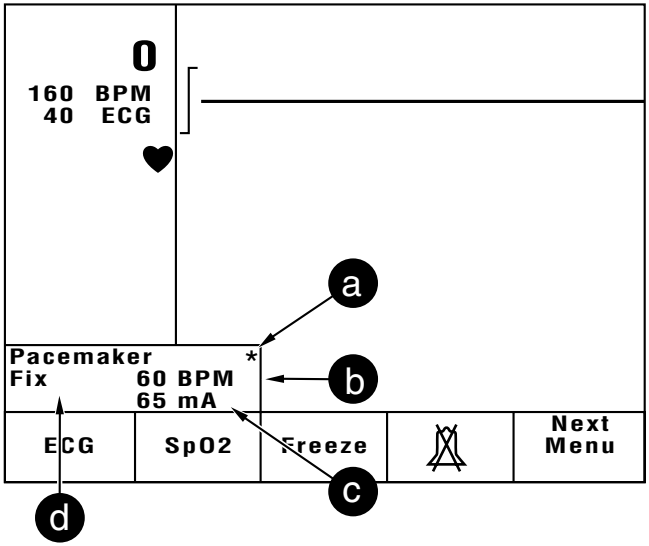

Figure 10-8. Screen display with pacemaker switched on

a asterisk, flashing with every delivered pacing pulse

b pacing rate

c pacing current

d pacing mode

☞ ***The default pacer rate can be preset (Defaults menu).***

* Press the Dem Fix button for 3 seconds to select the fixed-rate mode ("Demand" is replaced with "Fix" at **d** in Figure 10-8).

The asterisk (**a**; Figure 10-8) flashes each time a pacing pulse is **delivered**.

* Select the pacing rate with the buttons + P/min and P/min -.

* Press the + mA button to slowly increase the pacer output to a level which ensures consistent reponses from the heart.

* To verify the success of the treatment, watch the ECG on the screen.

* Increase the current by another 5 mA to ensure reliable pacing.

* At the end of the intervention, **first turn off the pacemaker, then remove the pads carefully.**
In order to turn off the pacemaker, button ⏻ must be held down for at least 2 seconds. This safety precaution has been taken to prevent the pacemaker being turned off inadvertently. For this reason it is not possible to switch off **CardioServ** while the pacemaker is still on.

11. Configuring the Defibrillator Settings

This section describes the instrument settings that can be modified to suit your personal needs and preferences, and how this is done.

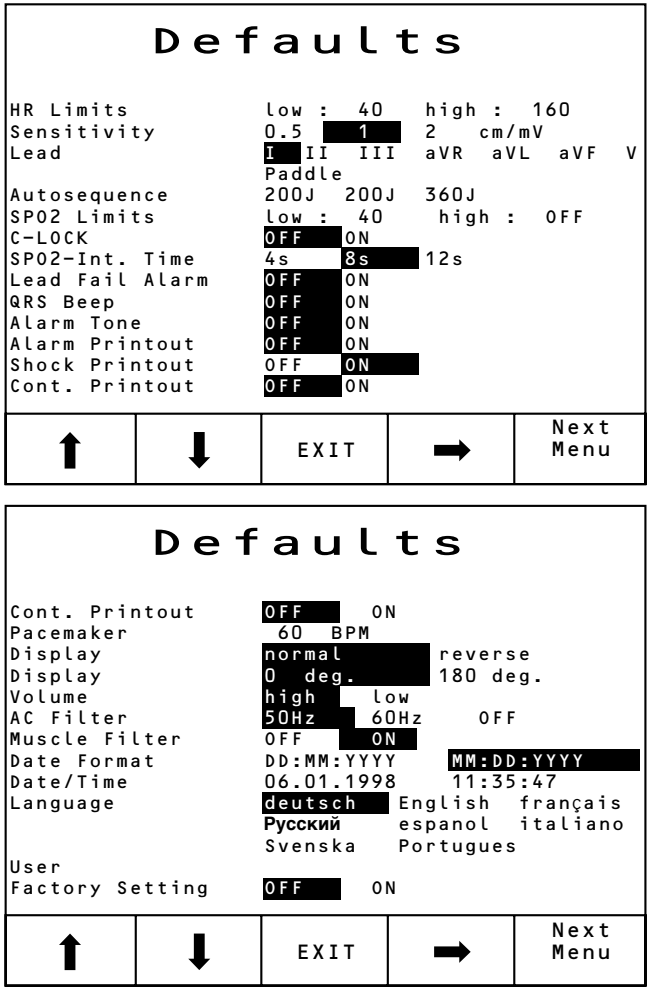

Figure 11-1. The menu

The defaults menu allows you to customize device settings, which means that they are retained in memory and are activated automatically on power up.

* Simultaneously press **F1** and **F5** to display the defaults menu.

Page 1 of the menu appears (Figure 11-1 top).

The cursor keys **F1**, **F2** (up/down) and **F4** (right) are used to move the cursor to the parameter whose setting is to be modified. Then you can change the setting with function keys **F1** through **F5**. The functions and labels of these keys change with each parameter.

With **F5** [Next Menu] you scroll to the next page of the menu.

Confirm each selection with **F5** [EXIT]. This will also take you back to the main menu.

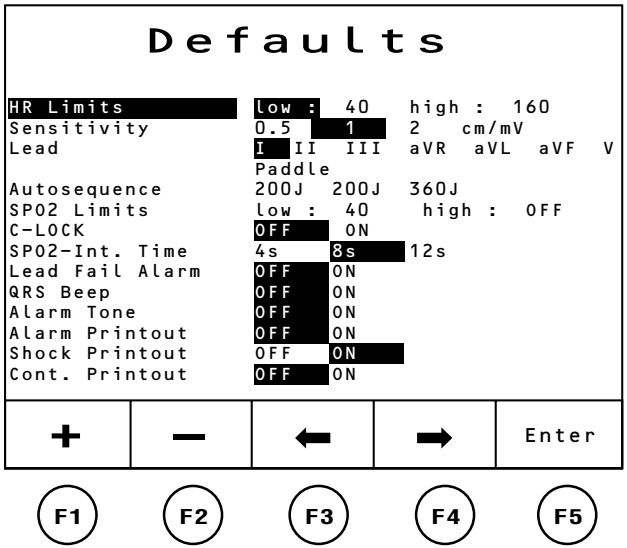

Figure 11-2. The configuration menu

With **F3** EXIT you leave the configuration menu and save the changes.

☞ *The new settings are saved only if you quit the defaults menu with F3* EXIT *.*

Warning *ECG monitoring is suspended during configuration.*

☞ *It is not possible to call up the defaults menu, while the defibrillator is charged, during ECG analysis (Analyse button) or while the pacemaker operates.*

Caution *When you display the defaults menu, the values preset in this menu will overwrite the temporary device settings (alarm limits, leads, etc.).*

HR Alarm Limits

The limit values for heart-rate monitoring selected here are automatically activated on power up.

* Using **F4**, move the cursor to the right.

* Adjust the low limit with **F1** and **F2** (if you keep the keys depressed, the digits change at a higher rate) (Figure 11-2). Alarm limits can be disabled by selecting a value outside the adjustment range.

* Using **F4**, move the cursor to the high limit and adjust it in the same way as the low limit.

* Confirm the new limit values with **F5.**

Sensitivity

The setting selected here (.5,1,2 cm/mV) is the **CardioServ** default sensitivity.

* Using **F4**, move the cursor to the right.

* Select the desired setting with **F3** or **F4** and confirm the selection with **F5**.

Lead

The setting selected here is the **CardioServ** default ECG lead.

* Using **F4**, move the cursor to the right.

* Select the desired lead with **F3** or **F4** and confirm the selection with **F5**.

Autosequence

This menu item defines the energy levels for the 1st, 2nd and 3rd defibrillation shock in autosequence mode (default: 200 J, 200 J, 360 J).

You can choose a different energy level (150 J, 200 J, 300 J, 360 J) for each shock.

When the cursor highlights a value, this value can be increased with **F1** and decreased with **F2.**

SpO_2 Limits

Here you adjust the default alarm limits for monitoring of SpO_2.

C-LOCK

Do you wish to have the C-LOCK ECG Synchronization feature enabled or disabled on power up?

SpO_2 Int. Time

Here you select the default integration time for averaging of the SpO_2 values. The 12 second integration time should only be selected in exceptional cases.

Lead Fail Alarm

Do you wish the alarm to sound after 30 s when an ECG electrode drops off?

QRS Beep

Do you wish to have the QRS beep enabled or disabled on power up?

Alarm Tone

Do you wish to have the audible alarm enabled or disabled on power up?

Alarm Printout

Do you want the recorder to start automatically in an alarm situation (violation of HR limits)?

Shock Printout

Do you want the recorder to start automatically when a defibrillation shock is delivered?

Continuous Printout

When the function is disabled, the recorder will stop automatically after 16 seconds. When it is enabled, the recorder must be stopped manually.

Pacemaker

This is to select the default pacing rate.

Display

Normal (black on white) or reverse (white on black) display on the LCD screen.

Normal or flipped display (rotating the display 180° may prove useful for CardioServ units operated in the defibrillator mounting system).

Volume

For selection of the volume of all audio signals emitted by the unit (prompts, alarms).

AC Filter

for elimination of signal noise from the power line. Default setting for 50 Hz (Europe) or 60 Hz (USA) or no filter (OFF).

Muscle Filter

For elimination of motion artifact and muscle action potentials (35 Hz).

Date Format

DD.MM.YYYY (European format) or
MM.DD.YYYY (US format).

Date / Time

For adjustment of date and time.

* Using **F4**, move the cursor to the right (day).
* Using **F1** and **F2**, adjust the day.
* Using **F4**, move the cursor to the right (month).
* Using **F1** and **F2**, adjust the month.
* Proceed in the same manner to adjust year, hours, minutes and seconds.
* Confirm the entries with **F5**.

☞ *Depending on the CardioServ model purchased, not all menu items may be available.*

Language

This menu item is used to select the language for the screen texts and printed documents.

* Using **F4**, move the cursor to the right.
* Select the desired language with **F3** or **F4**.
* Confirm your selection with **F5**.

User

Via this menu item you can enter a text or a name which will be printed in the margin of the recording strip.

* Using **F4**, move the cursor to the right.

You can now use **F1** and **F2** to select the first numeral, symbol or letter from a character set for the name or text to be entered. With **F1** you scroll forward through the set, with **F2**, backward. **F4** moves the cursor to the right, allowing you to enter the second character, etc. The first character is a blank.

* Confirm entries with **F5**.

Factory Settings

You can restore the factory settings by selecting ON (language and operating mode will not be changed).

☞ *Restoring the factory settings will delete the information entered with menu item "User".*

12. Error Indications and Messages

In this section of the manual you will find

- **the error indications and messages which CardioServ may display after the power-on self-test**
- **the error indications and messages which CardioServ may display while in use**
- **an explanation of the meaning of each message, and troubleshooting tips**

Error Messages during power-on self-test (POST)

Message	Effect	Explanation	Remedy
RAM Error	device defect, do not use the device		Notify service office
ROM Error	device defect, do not use the device		Notify service office
Display RAM Error press any key	restricted use for emergencies only, defibrillation possible	display defect, the display is difficult to read or cannot be read at all	Press one of the function keys (7) and notify service office
Error in fixed memory press any key	restricted use for emergencies only, defibrillation possible	user configuration defect (e.g., custom configurations cannot be saved)	Press one of the function keys (7) and notify service office
Time Base Error press any key	restricted use for emergencies only, defibrillation possible	all time-related data (such as the heart rate) may be erroneous	Press one of the function keys (7), adjust time; if error persists, notify service office
Check “Shock” key press any key	either buttons (**2**) and/or (**8**) were depressed on power up, or button(s) defective; when button defective, device cannot be used for defibrillations but for monitoring only		Press one of the function keys (7), switch off device, do not press keys (**2**) and (**8**) and switch device on again. If error message recurs, notify service office.
Check CHARGE key press any key (see “Shock” key above)	(see “Shock” key above)	(see “Shock” key above)	(see “Shock” key above)
Charge Energy Error press any key	stored energy differs from selected energy, use device in emergencies only!	error occurred last time the device was used (before it was turned off) and was saved	Press one of the function keys (7), deliver test discharge, switch device off and on again. If error message recurs, notify service office.

Messages/problems during operation

Message	Explanation	Remedy
Low battery	battery almost depleted	connect device to mains
HR alarm	violation of high or low HR limit, or no R-wave identified for 4 s	when patient is not asystolic,check electrodes; select another lead when the signal amplitude is too small
Check electrode	high ECG electrode or paddle impedance	check electrode technique
Defib charged	defibrillation energy stored for 30 s	
Check selector	energy selector is not indexing properly; defibrillation not possible	set energy selector to the exact position; when message recurs, notify service office
Energy high	selected energy exceeds 50 joules, even though internal paddles are connected; stored energy higher than selected energy; defibrillation possible	select a lower value (internal paddles), release test discharge; when message recurs, notify service office
Energy low	stored energy below selected energy; defibrillation possible	release test discharge; when message recurs, notify service office
Electrode	defib paddle or electrode monitoring defect, exchange of paddles with device turned on, defibrillation not possible	switch device off and on again (device must be switched off for paddle exchange); when message recurs, notify service office
Device does not function correctly	software disturbance	switch device off and on again
Check pace pads	excessive AC line interference	enable the AC line filter, check electrode application
Green LED does not illuminate during line power operation	defective power supply unit	notify service
Yellow LED does not illuminate during line power operation	defective battery or power supply unit	notify service

For your notes

13. Cleaning, Maintenance and Disposal

This section of the manual describes

- **how to clean and disinfect the device and the electrodes**
- **how to sterilize the internal electrodes**
- **how to clean and disinfect the suction electrodes**
- **how to perform routine maintenance on the device**

13.1 Cleaning, Disinfection and Sterilization

Danger

Before cleaning the device, disconnect it from the power line. Turn off the device before touching the contact susfaces of the paddles, and be careful not to switch it on again while cleaning it. Danger to life! As a safety precaution, remove the battery and disconnect the paddles from the defibrillator.

Device and Paddles

* Discard all disposable electrodes immediately after use to prevent inadvertent reuse.

* The paddles and their leads can be cleaned and disinfected by wiping them down with a gauze pad moistened in a cleaning solution. Before applying the paddles again, check that they have thoroughly dried.

* Clean the instrument surface with a cloth moistened in a cleaning solution. Take care that the solution does not enter the defibrillator enclosure.

Any hospital-grade cleaning solution and disinfectant containing up to 70% alcohol is suitable.

Caution

Do not use hot air to sterilize the internal defibrillation electrodes.

* The internal defibrillation electrodes are initially cleaned in the same way as external paddles. For electrodes and connection cables, low-temperature plasma sterilization is the recommended method. Alternative methods are ETO sterilization, water vapor (autoclave at 134 °C) or ionizing radiation. Internal electrodes must be sterilized after each resuscitation code.

Caution

The defibrillation electrodes and handles must be disconnected from the cable before autoclaving (arrow, Figure 13-2).

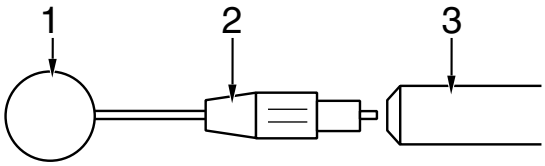

Figure 13-1. Inserting the contact paddle

☞ ***Having loosened the counter nut, you can easily alter the position of the contact paddle.***

To insert the contact paddles, proceed as follows:

* Screw the counter nut (**2**, Figure 13-1) onto the electrode as far as it will go.

* Screw the contact paddle (**1**) into the handle as far as it will go, then bring it into the appropriate position.

* Now fix the contact paddle by screwing the counter nut (**2**) tight against the handle (**3**).

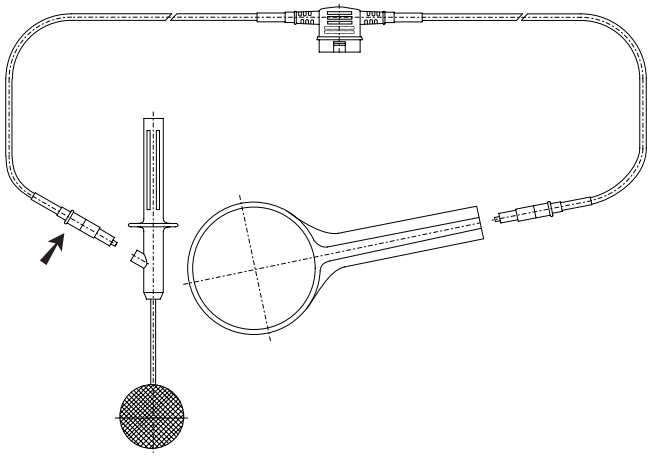

Figure 13-2. Counter electrode for internal defibrillation

External Counter Electrode for Internal Defibrillation

* Disconnect the electrode from its lead before cleaning or sterilizing it (Figure 13-2).

* Clean the electrode by rubbing it down with a cloth moistened in soap water. Use a disinfectant for disinfection. Do not immerse the electrode in the liquid.

* Low-temperature plasma sterilization is the recommended sterilization method. Alternative methods are ETO sterilization and ionizing radiation. (Please note: Frequently sterilizing the electrodes with ethylene oxide reduces the life of the plastic material!) Do **not** autoclave the electrodes!

Exchanging the Defibrillation Electrode Cable

* Switch off **CardioServ.**

* Grasp the plug and remove it from the socket (do not pull on the cable).

* When inserting the plug, observe the orientation (beveled edges) and click it into place.

Cleaning and Disinfecting Suction Electrodes

Do not use pointed metal objects to remove solid particles of dirt from the electrodes as this would destroy the silver/silver-chloride layer. Use a commercially available fiberglass eraser instead.

* Clean the electrodes with water and a detergent. Use a small brush to remove grime.

* All commercially available cleaning agents used for surgical instruments are suitable for cleaning of the electrodes. Follow the manufacturer's instructions to mix the preparation. Do not use metal dishes and take care not to immerse plugs and metal sockets in the solution.

* To disinfect the electrodes, wipe them down with a cloth moistened in 70% alcohol.

13.2 Maintenance

Before each application

* visually check the device and all accessories (leads, electrodes, etc.) for signs of damage

* test the device performance (refer to section 3).

If you detect damages or impaired functions so that the safety of the patient and user are no longer guaranteed, **CardioServ** must be repaired before it can be applied again.

Checks at regular intervals

CardioServ defibrillators are emergency medical devices designed to save and preserve life; they must be ready for use at all times. Operational readiness must also be ensured for battery power operation. Therefore, the devices must be subjected to the following checks at regular intervals:

Every month

* visually inspect the device and accessories

* test the device performance as described in section 3.

Battery Maintenance

Rechargeable batteries require special maintenance and continued checks to assure they function in emergency situations. It is normal for batteries of this type to self-discharge when not in use.

If batteries are repeatedly partially discharged, the resulting "memory effect" may dramatically reduce the battery capacity. This effect can be efficiently minimized by regular conditioning. If the capacity of a relatively new battery is drastically reduced, the battery may be reconditioned by repeated charging and discharging. Proper maintenance of NiCd batteries is essential and considerably promotes their proper performance. Routine preventive maintenance should be carried out by qualified service technicians on a regular basis (recommended interval: 30 days).

It is the user's decision whether or not to recondition the battery at regular intervals. Batteries which are not reconditioned have a shorter service life and will have to be replaced more frequently.

☞ *We recommend our Accu Service Unit (Figure 3-5) for optimal care of the batteries. It prolongs the batteries' service life and guarantees their operational readiness at all times.*

If you decide not to use the Accu Service Unit, the battery can be checked and reconditioned as described below. With this method, however, the continued operational readiness of CardioServ on battery power is not guaranteed.

1. Disconnect **CardioServ** from the power line and discharge fully charged battery in the monitoring mode. To do so, set energy selector switch to (SpO_2 sensor not connected) and wait until device switches off.

2. Check how long it takes before battery is depleted. If the time is less than 1.8 hours, the battery is too old or improperly maintained and should be replaced.

3. Recharge the battery. This will take 16 hours.

Technical Inspections

For safety, the devices require regular maintenance. To ensure functional and operational safety of the **CardioServ** Technical Inspections should be carried out annually.

The following checks can be carried out within the framework of a service contract. Otherwise it should be assured that the person inspecting the device is adequately trained and experienced.

* The device and accessories should be visually inspected for signs of mechanical damage which may impair the device functions.

* All safety-related labels and instructions printed on the device must be inspected for legibility.

* A performance test as described in section 3 is to be performed. The hardware and software functions are to be tested by means of the power-on self-test. All segments of the LCD must be visible.

* On the defibrillator the energy delivered into a 50-ohm resistance must be measured.

* The electrode leads of defibrillators and pacemakers must be carefully checked for signs of mechanical damage, short-circuits and breaks.

* After 2 years, replace all defibrillator and pacemaker batteries that were not maintained and reconditioned in our Accu Service Unit for CardioServ. Battery maintenance and reconditioning in the Accu Service Unit extends the battery life for about 1 year.

* The warning system of the defibrillator must be checked.

Testing the Pacemaker Performance

The performance of the pacemaker can be tested with a commercially available pacemaker tester (e.g. CS300 Simulator from GEMS IT, part no. 417 983-001).

* Devices which are not in perfect working order or the use of which is unsafe must be immediately repaired or labelled accordingly to prevent their use.

The device does not require any other maintenace.

13.3 Disposal of the Product

Do not dispose the product described in this Operator Manual with the normal, unsorted household waste. It requires separate treatment. Please contact an authorized representative of the manufacturer for information on disposal of the product.

14. Technical Specifications

The “Technical Specifications” section describes the technical data of the device valid at the time of printing.

Operating modes

* non-synchronized (defibrillation at any time)
* synchronized (cardioversion)

Energy selection

adjustable, energy to be delivered into 50 ohms displayed digitally

* Selectable energy levels, energy to be delivered into a 50-ohm resistance (max. energy of 50 joules for internal defibrillation):

  2
  5
  7
  10
  20
  30
  50
  100
  150
  200
  300
  360 joules

* possible deviation from selected energy below values specified by IEC

Energy storage

by means of capacitor, capacitor is charged from battery, from a 12-volt power source (emergency vehicle) or from the power line (95 to 240 V; 49 to 65 Hz); when capacitor charging is terminated buzzer sounds:

* capacitor charging time for energy setting of 360 J:
  – from power line: typically 8 s
  – from fully charged battery: typically 8 s
  – from partially discharged battery: typically 10 s (15 s max.),
    measured at least 5 minutes after 15 shocks of 360 joules each (for 200 joules typically 4 s)

Defibrillation pulse

capacitor discharge via induction coil (damped serial resonant circuit), pulse shape = a sinusoidal halfwave with decay period:

* pulse duration for an external resistance of 50 ohms approx. 4 ms, measured from the beginning of the pulse to the intersection of the zero line and the inflection point of the trailing pulse edge

* in synchronized mode the defibrillation pulse is released approx. 40 ms after the R-wave trigger

Discharge circuit

serial oscillating circuit in series with external resistance (patient):

* capacitance 32 µF
* inductance 26 mH
* equivalent resistance 6.5 ohms

Pulse output

isolated, no conductive connection with enclosure, opencircuit and short-circuit-proof

* isolation test voltage 8 kV DC, type CF according to IEC requirements

Safety discharge

capacitor discharge via internal load resistance:

* when the defibrillation shock is not triggered within 30 s after charging
* when the defibrillation shock is triggered, but the discharge circuit is interrupted, after approx. 0.2 s
* immediately when reducing the selected energy during or after charging
* when the selected energy is not reached, after 32 s
* in the event of technical malfunctions

Test features

* pilot lamp for battery charging
* defibrillator test by discharging the stored energy into the internal 50-ohm load resistance; 2-digit display of the delivered energy
* warning on LCD when discharge circuit is interrupted (e.g., defibrillation paddle not applied)
* automatic defibrillator test on power up with display of error message, if applicable

Synchronization

with ECG signal of either polarity:

* min. ECG amplitude for reliable triggering approx. 0.5 mV with QRS duration of 80 ms

ECG signal input via paddles

ECG signal acquisition via defibrillator paddles, ECG trace displayed on LCD, automatic switching to ECG electrodes when patient cable is connected; cardioversion both via ECG patient cable and via paddles; differential input; isolated, class CF according to IEC, with overvoltage protection

* input voltage range ±4mV
* input impedance > 1.5 Mohm
* max. polarization voltage ±1V
* frequency response 2.2 Hz to 20 Hz (-3 dB)
* common-mode rejection > 80 dB
* patient leakage current: in normal condition < 10 µA, in single-fault condition < 50 µA
* detection of pacing pulses
  – pulse duration d_p > approx. 0.1ms < 2.0 ms
  – pace marker independent of polarity
  – pulse amplitude a_p ±20 to ±700 mV
  – reverse-current pulse a_0 ±1 mV
  – time constant t_0 =25 to 100 ms

ECG signal input via patient cable

via ECG electrodes, automatic switching to ECG electrodes when patient cable is connected; cardioversion both via ECG electrodes and via paddles; differential input, symmetrically referred to N, isolated, class CF according to IEC; 7 standard leads selectable via lead selector; input with overvoltage protection (defibrillation-proof):

* input voltage range ±4.4 mV for recorder, ±4 mV for display
* input impedance > 2.5 Mohm for 10 Hz
* common-mode dynamic range ±3 V
* differential DC voltage compatibility ±1 V
* common-mode rejection (CMRR) R,L referred to N 65 dB, N referred to chassis >110 dB
* QRS trigger (measured according to AAMI EC 13): trigger threshold 0.3 mV (for QRS widths between 40 ms and 70 ms and between 30 and 250 BPM)
* bandwidth .5 to 100 Hz
* patient leakage current: in normal condition < 10 µA, in single-fault condition < 50 µA
* ground leakage current: in normal condition .5 mA, in single-fault condition 1 mA
* voltage resistance referred to circuit reference 4 kV
* detection of pacing pulses
  – pulse duration d_p > approx. 0.1ms < 2.0 ms
  – pace marker independent of polarity
  – pulse amplitude a_p ±20 to ±700 mV
  – reverse-current pulse a_0 ±1 mV
  – time constant t_0 =25 to 100 ms

Signal display

backlit LCD, 2-channel erase bar mode, calibration pulse in left-hand corner (for ECG)

alphanumeric presentation of alarm messages, sensitivity, leads, systole blinker, alarm limits, heart rate, energy and softkey labels

ECG freeze with simultaneous display of the current ECG and (for units with SpO2 function) plethysmogram at a smaller scale

ECG trace 1.5 times larger than on recording: with a sensitivity of 1 cm/mV a 1-mV signal has an amplitude of 1.5 cm on the display

* erase bar sweep speed 25 mm/s
* trace length in real-time mode 4.6 s
* display dimensions: 115 mm wide, 86 mm high
* resolution 320 x 240 pixels (pitch of .36 x .36 mm)
* displayed image can be rotated 180°

Signal transmission

signal input –> amplification –> signal sampling –>
AD conversion –> digital processing –> LCD and recorder

* selectable sensitivity: .5 – 1 – 2 cm/mV (with max. sensitivity of 2 cm/mV a 1-mV input signal is 2 cm in amplitude on the recorder and about 3 cm on the LCD), amplitude limited to approx. ±2 cm on the recorder and approx. ±3 cm on the LCD
* signal sampling rate 1000 Hz at mains frequency of 50 Hz, 1200 Hz at mains frequency of 60 Hz

ECG signal output ("Option" port)

* ECG lead shown on display
* 1 V output signal for 1 mV input signal (at 1 cm/mV)
* U_{max} ± 2 V
* overall error < 3% (typical)
* R_L 500 Ω min.
* delay < 150 ms (not suitable for precise triggering)

9 = ECG
10 = chassis

Systole check

* heart symbol flashing on the LCD
* QRS beep (can be disabled)
* AC line filter 50 Hz (60 Hz); interference elimination
* muscle filter
  low pass filter with f_{lim} = 27 Hz (50 Hz mains)
  f_{lim} = 32 Hz (60 Hz mains)
  cut-off at 83/100 Hz

Heart-rate measurement

derivation of trigger pulses from the ECG of either polarity, adaptive trigger threshold, calculation of the average rate, storage of the result, 3-digit display on LCD, alarm limits to the left of the reading:

* measuring range 15 to 300 BPM
* digit height of HR reading 7.5 mm
* digit height of alarm limits 2.5 mm
* min. amplitude for reliable triggering > 2.5 mV for ECG signal with a QRS duration of 80 ms

Alarm system

electronic realease of alarm

* when the HR violates one of the set limits for at least 5 s: alarm tone sounds (can be disabled), message “Alarm, high HR” or “Alarm, low HR”, recorder starts (if configured)
* when at least one of the selected electrodes drops off: audible signal (if patient cable is plugged in), message “Alarm, Electrode” on display
* alarm limits adjustment range 15 to 300 BPM (not overlapping)
* digit height of alarm limits 2.5 mm
* keys to cancel alarm and to silence alarm tone
* softkeys to adjust alarm limits

Recording

delayed recording of the ECG stored in the signal memory (strip length 16 s, incl. 4-s history) in the event of an alarm plus alphanumeric annotations on the paper margin:

– heart rate
– lead
– filter
– date
– time
– paperspeed
– cause of recording (defib, alarm, manual)
– selected energy
– delivered energy
– sync mark
– text (name of user/hospital/practice)

After the ECG recording, a patient ID sheet is printed indicating name, date of birth, user, comments, date, time, energy and alarm limits.

Direct writing with rectangular coordinates using thermorecording technology (printhead with electronically controlled thermal elements records on thermosensitive paper), baseline fixed at the center of the space available for recording of the ECG trace, grid imprint, roll paper, paper transport by electronically controlled DC motor, limited duration of transport

* number of recording channels 2

* paper width 55 mm

* roll diameter 60 mm max. (roll with 40 m of GEMS IT CONTRAST® chart paper)

* printhead resolution vertical 6 dots/mm, horizontal 24 dots/mm

* paper speed 25 mm/s ±5%

* paper transport after both manual and automatic start 16 s (incl. history of 4 s after automatic recorder start)

To prevent damage to the printhead, use only the original GEMS IT CONTRAST® chart paper.

Memory

* storage of 40 ECG strips initiated by defibrillation or alarm with a length of 16 seconds and a history of 4 seconds each, incl. a full report

* storage of the 80 most recent actions (e.g., power on, power off, alarms, defibrillation energy) incl. date and time

SpO_2

* saturation: 0 to 100 %, in 1-% increments
* rate: 0 to 250 BPM, in 1-BPM increments
* alarm limit: off, 15 to 100 %
* display of plethysmogram
* C-LOCK ECG synchronization
* integration time: 4, 8 and 12 seconds
* measuring accuracy: 70 to 100% ± 2 digits
  50 to 69% ± 3 digits
  pulse display 1.2% or ± 1 BPM

Pacemaker

* operating modes: demand, fixed-rate
* pacing rate: 30 to 180 BPM, ±5%
* pacing current: 0 to 200 mA (for 500 Ohms), voltage up to 120 V, ±5%
* pulse width: 40 ms
  20 ms (for pacing rate of 150 BPM and higher)
* pulse shape: monophase square-wave pulse
* refractory period: 100 ms

Power

from the power line

* 95 V to 240 V, 49 Hz to 65 Hz
* power consumption at 230 V
  – during monitoring 160 mA
  – during capacitor charging 750 mA
* from a 12-Volt power source of the emergency vehicle
* from exchangeable, rechargeable NiCd batteries
* rated voltage 12 V
* rated capacity 1.4 Ah
* battery is charged while inserted in the unit
* charging time for depleted battery approx. 16 hours
* operating time with a fully charged battery approx. 35 defibrillation shocks of 360 joules each (into 50 ohms) or 3 hours of monitor operation (1.2 hours with pacemaker and SpO_2 measuring system)

Operational readiness

4 s after power up (incl. automatic selftest)

Operating position

any

Environment

Operation

under the following conditions regarded as normal:

* temperature between 0 and +40 °C
* rel. humidity between 30 and 95%, no condensation
* atmospheric pressure between 700 and 1060 hPa

Storage and transport

* temperature between -20 and +60 °C
* rel. humidity between 10 and 95%, no condensation
* atmospheric pressure between 500 and 1060 hPa

Dimensions

* width 432 mm
* height 172 mm
* depth 377 mm

Weight

* approx. 8 kg (incl. battery)

For your notes

15. Order Information and Accessories

Subject to change, always refer to latest list of accessories.

101 117 01	**CardioServ** defibrillator with ECG monitor and recorder
101 117 03	as above, plus pacemaker
101 117 04	as above, plus SpO_2 measuring system
101 117 05	as above, plus pacemaker and SpO_2 measuring system

Accessories

227 446 32	Operator's Manual
241 056 01	Standard accessory kit (5-wire cable)
241 056 02	Standard accessory kit (3-wire cable)
931 098 68	CardioServ accessory bag
931 099 40	CardioServ carrying bag
226 130 02	Recording chart paper, width 55 mm, length 40 m
919 062 00	Power cord, Euro
401855-107	Power cord, CH
919 203 37	Power cord, UK
303 440 30	Battery 12 V, 1.4 Ah
202 307 01	Defibrillator mounting system with power supply
202 307 02	Wall-mount system with quick-action locks (w/o. power supply)
205 106 01	External charging unit (only for use with C**ardioServ** models which have been modified accordingly)

ECG

223 400 11	Patient trunk cable, 5 leads, 2.2 m length, **to be used with**
384 017 78	5-lead electrode cable (R,L,F,N,C) without HF protective resistors, 0.7 m length, with clip connector (press stud contact) or
223 404 25	Electrode lead, white (C), 1 m length, with 4-mm connector
223 288 01	Patient cable, 3 leads, 2.2 m length, with clip connector (press stud)
919 200 31	disposable adhesive electrode, silver/silver chloride, pregelled, 20 mm contact area, pkg. of 200
217 144 01	Chest suction electrode with small suction ball
217 320 01	Electrode for children, with press-stud connection
217 123 01	Adhesive rings for above electrode

217 321 01	Electrode for adults, with press-stud connection
927 223 00	Adhesive rings (pkg. of 500) for electrode 217 321 01
217 083 05	Electrode cream, pkg. of 10 tubes
217 083 18	Electrode cream, 250-ml bottle (refilling)
217 083 14	Electrode cream, 5-1 container
930 115 82	Dispenser, 30 ml

Defibrillation

217 304 03	Pair of defib paddles for external defibrillation, with discharge buttons
303 439 96	Contact insert for external defibrillation electrode (1)
303 439 95	Clip-on electrode for children (1) (external defib paddles)
217 308 01	Pair of defib electrodes for internal defibrillation, w/o. contact insert, to be used with
384 013 19	Contact inserts (2), internal, for adults
384 013 20	Contact inserts (2), internal, for children
384 013 21	Contact inserts (2), internal, for small children
217 329 01	Defibrillator electrode, anterior-posterior
919 202 94	Disposable adult pad for defibrillation and pacing, rectangular
919 202 95	as above, but for children
223 383 01	Connection cable for pads 919 202 94/95
919 201 89	Disposable adhesive defibrillation electrode for adults (also for pacing), round
919 207 75	Disposable adhesive defibrillation electrode for children (also for pacing), round
223 346 01	Adapter lead for disposable adhesive defibrillation electrode
919 202 36	External counter electrode for internal defibrillation

SpO_2

303 443 58	Connection cable (length 3 m) for the following sensors and for units before SN 101157662
2026751-001	Connection cable (length 3 m) for the following sensors and for units with SN 101157662 and later
701 240 21	Standard finger sensor for adults weighing more than 40 kg, reusable, model DS-100 A
701 240 22	Disposable sensor for children and adults (10 to 50 kg), flexible, model D-20, 24/cs.

701 240 26	Disposable sensor for children (1 to 20 kg), flexible, model I-20, 24/cs.
701 240 27	Disposable sensor for adults >30 kg, flexible, model D-25, 24/cs.
701 240 32	Disposable sensor for neonates < 3 kg and for adults > 50 kg, 24/cs.

Pacing

919 202 94	Disposable adult pad for defibrillation and pacing, rectangular
919 202 95	Disposable pediatric pads for defibrillation and pacing, rectangular
223 383 01	Adapter lead for disposable pad 919 202 94/95
919 201 89	Disposable adult pad for defibrillation and pacing (requires adapter lead)
919 202 75	as above, but for children
223 346 01	Adapter lead for disposable pads 919 201 89, 919 202 75

Electromagnetic Compatibility (EMC)

Changes or modification to this system not expressly approved by GE Medical System could cause EMC issues with this or other equipment. This system is designed and tested to comply with applicable regulation regarding EMC and needs to be installed and put into service according to the EMC information stated as follows.

Use of portable phones or other radio frequency (RF) emitting equipment near the system may cause unexpected or adverse operation.

The equipment or system should not be used adjacent to, or stacked with, other equipment. If adjacent or stacked use is necessary, the equipment or system should be tested to verify normal operation in the configuration in which it is being used.

Guidance and Manufacturer's Declaration – Electromagnetic Emissions

The CardioServ defibrillator is intended for use in the electromagnetic environment specified below. It is the responsibility of the customer or user to ensure that the CardioServ defibrillator is used in such an environment.

Emissions Test	Compliance	Electromagnetic Environment – Guidance
RF emissions CISPR11	Group 1	The equipment uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR11	Class B	The equipment is suitable for use in all establishments including domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic Emissions EN 61000-3-2	Class A	
Voltage fluctuations / Flicker emissions EN 61000-3-3	Complies	

Guidance and Manufacturer's Declaration – Electromagnetic Immunity			
The CardioServ defibrillator is intended for use in the electromagnetic environment specified below. It is the responsibility of the customer or user to ensure that the CardioServ defibrillator is used in such an environment.			
Immunity Test	**EN 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment – Guidance**
Electrostatic discharge (ESD) EN 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/ burst EN 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines The product has no input or output lines.	Mains power should be that of a typical commercial or hospital environment
Surge EN 61000-4-5	± 1 kV differential mode ± 2 kV common mode	± 1 kV differential mode ± 2 kV common mode	Mains power should be that of a typical commercial or hospital environment
Voltage dips, short interruptions and voltage variations on power supply input lines EN 61000-4-11	< 5% U_t (> 95% dip in U_t) for 0.5 cycles 40% U_t (60% dip in U_t) for 5 cycles 70% U_t (30% dip in U_t) für25 cycles < 5% U_t (> 95% dip in U_t) for 5 s	< 5% U_t (> 95% dip in U_t) for 0.5 cycles 40% U_t (60% dip in U_t) for 5 cycles 70% U_t (30% dip in U_t) for 25 cycles < 5% U_t (> 95% dip in U_t) for 5 s	Mains power should be that of a typical commercial or hospital environment. If the user of the CardioServ defibrillator requires continued operation during power mains interruptions, it is recommended that the CardioServ defibrillator be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field EN 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristics of a typical location in a typical commercial or hospital environment.
NOTE U_t is the AC mains voltage prior to application of the test level.			

Guidance and Manufacturer's Declaration – Electromagnetic Immunity

The CardioServ defibrillator is intended for use in the electromagnetic environment specified below. It is the responsibility of the customer or use to assure that the CardioServ defibrillator is used in such an environment.

Immunity Test	EN 60601 Test Level	Compliance Level	Electromagnetic Environment – Guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the CardioServ defibrillator, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance**
Conducted RF EN 61000-4-6	3 V_{rms} 150 KHz to 80 MHz outside ISM bands[a]	10 V_{rms}	$d = 0.35\sqrt{P}$
	10 V_{rms} 150 KHz to 80 MHz in side ISM bands[a]	10 V_{rms}	$d = 1.2\sqrt{P}$
Radiated RF EN 61000-4-3	10 V/m 80 MHz to 2.5 GHz	10 V/m	$d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).[b] Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[c], should be less than the compliance level in each frequency range.[d] Interference may occur in the vicinity of equipment marked with the following symbol:

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

a The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz.

b The compliance level in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2.5 GHz are intended to decrease the likelihood that mobile/portable communications equipment could cause interference if it is advertently brought into patient areas. For this reason, an additional factor of 10/3 is used in calculating the recommended separation distance fro transmitter in these frequency ranges.

c Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radio, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, and electromagnetic site survey should be considered. If the measured field strength in the location in which the equipment is used exceeds the applicable RF compliance level above, the equipment should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the equipment.

d Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 10 V/m.

Recommended Separation Distances

The table below provides the recommended separation distances (in meters) between portable and mobile RF communication equipment and the CardioServ defibrillator.

The CardioServ defibrillator is intended for use in the electromagnetic environment on which radiated RF disturbances are controlled. The customer or the user of the CardioServ defibrillator can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the CardioServ defibrillator as recommended below, according to the maximum output power of the communications equipment.

Rated Maximum Output Power of Transmitter in Watts	**Separation Distance in Meters (m) According to Frequency of Transmitter**			
	150 kHz to 80 MHz outside ISM bands $d = 0.35\sqrt{P}$	**150 kHz to 80 MHz in ISM bands** $d = 1.2\sqrt{P}$	**80 MHz to 800 MHz** $d = 1.2\sqrt{P}$	**800 MHz to 2,5 GHz** $d = 2.3\sqrt{P}$
0.01	0.04	0.12	0.12	0.28
0.1	0.11	0.38	0.38	0.87
1	0.35	1.2	1.2	2.8
10	1.1	3.8	3.8	8.7
100	3.5	12	12	28

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 The ISM (industrial, scientific and medical) bands between 150kHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 to 13.567 MHz; 26.957 to 27.283 MHz; and 40.66MHz to 40.70 MHz.

For transmitters rated at a maximum output power not listed above, the recommended separation distance [*d*] in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE These guidelines may not apply in all instances. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Compliant Cables and Accessories

The use of accessories, transducers and cables other than those specified may result in increased emissions or decreased immunity performance of the equipment or system.

The table below lists cables, transducers, and other applicable accessories with which GE Medical Systems claims EMC compliance.

NOTE: Any supplied accessories that do not affect EMC compliance are not included.

Part No	Description
223 400 11	Patient trunk cable, 5 leads
384 017 78	5-lead electrode cable
223 404 25	Electrode lead, white
223 288 01	Patient cable, 3 leads
217 304 03	Pair of defib paddles, external
217 308 01	Pair of defib paddles, internal
223 383 01	Connection cable for pads
223 346 01	Adapter lead for pads
303 443 58	Connection cable for SpO_2 sensor
701 240 XX	Disposable sensor for SpO_2
407705-005	Disposable nasal SpO_2 sensor
919 062 00	Power cord, Euro

919 203 37 Power cord, UK

401855-107 Power cord, CH

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2019524-001 Rev B